



SaltLake-200175.1 0011502-00015

RELATED APPLICATIONS

This application is a continuation-in-part patent application of U.S. Patent Application Serial No. 09/460,740 entitled Compression Plate Anastomosis Apparatus which was filed on December 14, 1999 on behalf of Duane D. Blatter, Kenneth C. Goodrich, Mike Barrus, and Bruce M. Burnett. Serial No. 09/460,740 is incorporated herein by specific reference. The present application is also a continuation-in-part patent application of U.S. Patent Application Serial No. 09/293,617 entitled Anastomosis Apparatus For Use In Intraluminally Directed Vascular Anastomosis which was filed on April 16, 1999 on behalf of Duane D. Blatter. Serial No. 09/293,617 is incorporated herein by specific reference.

BACKGROUND OF THE INVENTION

1. The Field of the Invention

The present invention is directed generally to anastomosis methods, systems and devices. More specifically the present invention is directed to compression plate vascular anastomosis methods, systems and devices with the use of a vascular anvil.

2. Relevant Technology

Endoscopic applications are generally used in intracavity procedures such as intrathoracic and intraabdominal procedures. Peripheral techniques are usually employed in other body regions, such as arms and legs. It is desirable to be able to provide by active endoscopic or peripheral procedures a variety of medical services that are currently provided by techniques that are more invasive and more demanding in time and in medical resources and skills. This goal is justified by the efficiency, effectiveness, safety, low cost, and preventive accomplishments of active endoscopic or peripheral procedures. In particular, this invention provides new methods, devices and systems for

1 performing vascular anastomoses by intraluminally directed active endoscopic or
2 peripheral procedures. The intraluminally directed or intravascular part of the procedures
3 of this invention is based on an examination performed by, for example, fluoroscopy, and
4 extraluminal manipulation is performed endoscopically or according to a peripheral
5 technique.

6 One aspect of this invention encompasses the quasi-simultaneity of the
7 exploration, diagnosis and corrective tasks that can be achieved in vascular anastomoses
8 performed by the active endoscopic or peripheral procedures of this invention. Another
9 aspect of this invention includes the minimally invasive character of the vascular
10 anastomoses that are performed by the active endoscopic or peripheral procedures of this
11 invention. These procedures are also characterized by comparatively reduced
12 requirements of medical facilities and skill. To more effectively describe and enable the
13 present invention, a review of some basic terminology and related technology is offered
14 in the immediately following subsections.

15 **2.1. Terminology**

16 An anastomosis is an operative union of two hollow or tubular structures.
17 Anastomotic structures can be part of a variety of systems, such as the vascular system,
18 the digestive system or the genitourinary system. For example, blood is shunted from an
19 artery to a vein in an arteriovenous anastomosis, and from the right pulmonary artery to
20 the superior vena cava in a cavopulmonary anastomosis. In other examples, afferent and
21 efferent loops of jejunum are joined in a Braun's anastomosis after gastroenteroscopy; the
22 ureter and the Fallopian tube are joined in a ureterotubal anastomosis, and the ureter and
23 a segment of the sigmoid colon are joined in a ureterosigmoid anastomosis. In
24 microvascular anastomosis, very small blood vessels are anastomosed usually under
25 surgical microscope.
26

1 An anastomosis is termed end-to-end when the terminal portions of tubular
2 structures are anastomosed, and it is termed end-to-side when the terminal portion of a
3 tubular structure is anastomosed to a lateral portion of another tubular or hollow
4 structure. In an end-to-side anastomosis, we often refer to the structure whose end is
5 anastomosed as the "graft vessel" while the structure whose side wall is anastomosed is
6 referred to as the "receiving structure".

7 Anastomotic material typically includes autologous material, but it can also
8 include heterologous material or synthetic material. An autologous graft is a graft in
9 which the donor and recipient areas are in the same individual. Heterologous material is
10 derived from an animal of a different species. The graft can be made of a synthetic
11 material such as expanded polytetrafluoroethylene ("ePTFE"). Wolf Dieter Brittinger,
12 Gottfried Walker, Wolf-Dieter Twittenhoff, and Norbert Konrad, *Vascular Access for
Hemodialysis in Children, Pediatric Nephrology*, Vol. 11 (1997) pp. 87-95.

13 A nonocclusive anastomosis is typically an end-to-side anastomosis in which the
14 flow of matter through the vessel that is anastomosed in its side is not interrupted while
15 the anastomosis is performed. Most conventional techniques for vascular anastomosis
16 require the interruption of blood flow through the receiving vessel while the anastomosis
17 is performed.

18 Although the parts of a blood vessel are designated by well-known terms in the
19 art, a few of these parts are briefly characterized here for introducing basic terminology.
20 A blood vessel is in essence a tubular structure. In general, the region comprised within
21 tubular walls, such as those defining a blood vessel or the walls defining the tubular
22 member of an endoscope, is termed the lumen or the intraluminal space. A lumen that is
23 not occluded is a patent lumen and the higher the patency of a blood vessel, the less
24 disrupted the blood flow through such vessel is. A reduction of a blood vessel's patency
25 can be caused by a stenosis, which is generally a stricture or narrowing of the blood
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1 vessel's lumen. A hyperplasia, or tissue growth, can also reduce a blood vessel's
2 patency. Reduction of blood vessel patency, and in general a disruption in a vessel's
3 blood flow, can lead to ischemia, which is a local lack of oxygen in tissue due to a
4 mechanical obstruction of the blood supply.

5 A stent is a device that can be used within the lumen of tubular structures to
6 assure patency of an intact but contracted lumen. Placement of a stent within an occluded
7 blood vessel is one way of performing an angioplasty, which is an operation for enlarging
8 a narrowed vascular lumen. Angioplasty and bypass are different ways for reestablishing
9 blood supply, an operation that is called revascularization.

10 A blood vessel is composed of three distinct layers. From inside to outside, these
11 layers include the intima, the media and the adventitia. The intima is a single layer of flat
12 cells that collectively line the lumen. The media is a thick middle layer composed of
13 smooth muscle cells. The adventitia is an outer layer that comprises fibrous covering.

14 Angiography is a technique for performing a radiograph of vessels after the
15 injection of a radio-opaque contrast material. This technique usually requires
16 percutaneous injection of a radio-opaque catheter and positioning under fluoroscopic
17 control. An angiogram is a radiograph obtained by angiography. Fluoroscopy is an
18 examination technique with an apparatus, the fluoroscope, that renders visible the
19 patterns of X-rays which have passed through a body under examination.

20 **2.2 Related Technology**

21 The operative union of two hollow or tubular structures requires that the
22 anastomosis be tight with respect to the flow of matter through such structures and also
23 that the anastomosed structures remain patent for allowing an uninterrupted flow of
24 matter therethrough. For example, anastomosed blood vessels should not leak at the
25 anastomosis site, the anastomotic devices should not significantly disrupt the flow of
26

1 blood, and the anastomosis itself should not cause a biological reaction that could lead to
2 an obstruction of the anastomosed blood vessels. In particular, anastomosed blood
3 vessels should remain patent and they should ideally not develop hyperplasia,
4 thrombosis, spasms or arteriosclerosis.

5 Because anastomosed structures are composed of tissues that are susceptible to
6 damage, the anastomosis should furthermore not be significantly detrimental to the
7 integrity of these tissues. For example, injury to endothelial tissue and exposure of
8 subintimal connective tissue should be minimized or even eliminated in vascular
9 anastomosis.

10 Because structures to be anastomosed are internal, an anastomosis requires a
11 degree of invasion. The invasive character of an anastomosis, however, should be
12 minimized subject to the reliable performance of a satisfactory anastomosis.
13 Accordingly, there has been a noticeable trend during the last quarter of this century
14 towards less invasive surgical intervention, a surgical style that is termed minimally
15 invasive surgery. This style is characterized by pursuing a maximal treatment effect with
16 minimal damage to surrounding and overlying normal structures. In addition, successful
17 minimally invasive procedures should procure patency and they should minimize damage
18 to the tissues of the anastomosed structures themselves.

19 A plurality of factors provide a propitious environment for this trend towards
20 minimally invasive surgery. These factors include the development of high-technology
21 diagnostic devices, the innate characteristics of human psychology and economic
22 imperatives.

23 High-technology diagnostic devices such as flexible fiber-optic endoscopes and
24 intravascular catheters have considerably enhanced our ability for performing a reliable
25 spacio-temporal location of disease. More specifically, these devices permit the early and
26 accurate determination of disease processes and their loci. Furthermore, it is known that

1 the earlier a tumor or growth can be identified, the more responsive it is to therapy by a
2 minimally invasive technique. See Rodney Perkins, *Lasers in Medicine in Lasers -*
3 *Invention to Application*, edited by John R. Whinnery, Jesse H. Ausubel, and H. Dale
4 Langford, p. 104, National Academy of Engineering, National Academy Press,
5 Washington, D.C. 1987. (This article will hereinafter be referred to as "*Lasers -*
6 *Invention to Application*"). See also Edward R. Stephenson, Sachin Sankholkar,
7 Christopher T. Ducko, and Ralph J. Damiano, *Robotically Assisted Microsurgery for*
8 *Endoscopic Coronary Artery Bypass Grafting*, *Annals of Thoracic Surgery*, Vol. 66
9 (1998) p. 1064. (This article will hereinafter be referred to as "*Endoscopic Coronary*
10 *Artery Bypass Grafting*").

11 Human psychology also contributes to the growing trend towards minimally
12 invasive techniques. This is attributed to the accepted prevailing preference of a
13 minimally invasive technique with respect to a more invasive surgical technique
14 whenever the outcomes of these two techniques are equivalent.

15 Finally, minimally invasive techniques are generally cost effective to insurers
16 and to society in general because they are performed on an outpatient basis or else they
17 require comparatively shorter hospitalization time. Furthermore, the less tissue is
18 invasively effected in a procedure, the more likely it is that the patient will recover in a
19 comparatively shorter period of time with lower cost hospitalization. Therefore,
20 economic factors also favor the development of minimally invasive techniques because
21 they can be performed with lower morbidity risk and they satisfy economic imperatives
22 such as reduced cost and reduced loss of productive time. See Rodney Perkins in *Lasers*
23 *- Invention to Application*, p. 104; *Endoscopic Coronary Artery Bypass Grafting*, pp.
24 1064, 1067.

25 Particularly in the field of vascular anastomosis, it is acknowledged that there is
26 an increasing demand for an easier, quicker, less damaging, but reliable procedure to

1 create vascular anastomosis. This demand is further revitalized by the movement of
2 vascular procedures towards minimally invasive procedures. See Paul M. N. Werker and
3 Moshe Kon, *Review of Facilitated Approaches to Vascular Anastomosis Surgery, Annals*
4 *of Thoracic Surgery*, Vol. 63 (1997) pp. S122-S127. (This work will hereinafter be
5 referred to as "*Review of Facilitated Approaches to Vascular Anastomosis*").

6 Conventional exploration and anastomosis techniques are not always
7 implemented in such a way as to satisfy the demand for an easier, quicker, less damaging,
8 but reliable vascular anastomosis. The following overview of conventional exploration
9 and anastomosis techniques closes this background section on related technology.

10 Exploration of a blood vessel typically provides necessary information for
11 locating and diagnosing vascular abnormalities such as those that reduce vascular
12 patency. This exploration can rely on examination techniques such as angiography and
13 endoscopy. Vascular abnormalities are usually detected fluoroscopically according to an
14 angiography procedure. When it is concluded that the appropriate corrective action
15 requires an anastomosis, conventional procedures ordinarily follow a sequence in which
16 the anastomosis is not performed at the time when the initial exploration and diagnostic
17 are performed, but at a later time and in a typically different clinical setup. Accordingly,
18 the time and resources that are spent during the exploration and diagnostic phases are not
19 directly employed in the performance of an appropriate corrective action, such as an
20 anastomosis.

21 By performing an anastomosis considerably after the initial exploration has taken
22 place and in a different location and clinical environment, these conventional procedures
23 also waste a significant part of the information acquired at the exploration phase. Images
24 obtained during an angiographic procedure are typically recorded on film or digital
25 medium. In current clinical practice, these recorded images are reviewed in a subsequent
26 clinical setting and based upon a knowledge of external anatomy, the lesion location and

1 optimal site for anastomosis are estimated. This process sacrifices potentially useful
2 information. Fluoroscopic visualization is no longer available without repeating the
3 angiogram procedure, and in conventional practice external anatomic localization is used
4 in correlation with previously recorded images. In addition to this external inspection,
5 conventional procedures could rely on imaging for determining the optimal anastomosis
6 site when corrective action is taken. However, having to reacquire information leads to a
7 waste of resources, it significantly increases the period of time from exploration to
8 corrective action, it is an additional burden on the patient, and it enhances the invasive
9 character of the treatment that is administered to the patient. Furthermore, reacquisition
10 of information might have to be done in an environment that demands higher skills and
11 more resources than they would have been otherwise needed. For example, the opening
12 of a body cavity to expose the anatomical region around a potential anastomosis site, the
13 determination of the optimal anastomosis site by external inspection, and the surgical
14 performance of the anastomosis are part of a treatment that is more complex, requires
15 practitioners with more training, and may be more time and resource consuming than the
16 treatment provided by the methods, systems and apparatuses of the present invention.

17 Vascular anastomosis techniques can be classified in a plurality of groups.
18 Although with various degrees of success, all these techniques generally intend to
19 provide leak-proof joints that are not susceptible to mechanical failure, and they also
20 intend to minimize damage and reduce the undesirable effects of certain operational
21 features that may lead to post-anastomosis complications. Damage to be minimized and
22 operational features whose undesirable effects should be reduced include endothelial
23 coverage injury, exposure of subintimal connective tissue, exposure of an intraluminal
24 foreign component, blood flow interruption, irregularities at the junction, adventitial
25 tissue stripping, intimal injury, installment of a foreign rigid body, use of materials that
26 may have toxic effects, damage to surrounding tissue, extensive vessel eversion, and

1 tissue plane malalignment. Post-anastomosis complications include intimal hyperplasia,
2 atherosclerosis, thrombosis, stenosis, tissue necrosis, vascular wall thinning, and
3 aneurism formation. In addition, vascular anastomosis techniques are characterized by
4 varying abilities to successfully cope with the dilating character of the structures to be
5 anastomosed, their diversity in size, and the possibility that at least one structure may
6 grow after the anastomosis has been performed. Other variables that partially determine
7 the suitability of a specific anastomosis technique include the nature of the material to be
8 anastomosed (for example, autologous, heterologous, or synthetic), the desired reduction
9 in operative time, the skill requirements, and the healing time.

10 Each one of the techniques discussed hereinbelow for joining anastomosed
11 structures presents a compromise for reducing undesirable effects in the practice of
12 vascular anastomosis. High standards in one or a few aspects of the anastomosis can
13 sometimes be achieved only at the expense of sacrificing what otherwise would have
14 been the benefits of other aspects of the anastomosis.

15 Since early in the 20th century when vessel anastomoses were performed with an
16 acceptable degree of reliability, the standard for creation of a vascular anastomosis has
17 been manual suturing. *Review of Facilitated Approaches to Vascular Anastomosis*, p.
18 S122. Suturing devices and methods are still being developed with the aim at performing
19 less invasive surgical procedures within a body cavity. See, for example, U.S. Pat. No.
20 5,860,992 disclosing devices and methods for suture placement while performing less
21 invasive procedures.

22 Regarding the application of sutures in vascular anastomoses, it has been
23 generally reported that "the insertion of transmural stitches, even in experienced hands
24 that employ atraumatic techniques and fine sutures, causes significant damage to the
25 vessel wall. As the result of this the subendothelial matrix becomes exposed to the
26 bloodstream and initiates the formation of a thrombus. The same process takes place at

1 the actual site of the anastomosis in the case of intima-intima apposition. These
2 processes are multifactorial but can cause obstruction of the complete anastomosis,
3 especially in small vessels.” *Review of Facilitated Approaches to Vascular Anastomosis*,
4 p. S122. In addition to proximal occlusion, needle-and-suture-mediated intimal
5 penetration is believed to represent a source of platelet emboli, which can cause distal
6 embolization and thus a hazard in brain revascularization and myocardial circulation.
7 Patrick Nataf, Wolff Kirsch, Arthur C. Hill, Toomas Anton, Yong Hua Zhu, Ramzi
8 Ramadan, Leonardo Lima, Alain Pavie, Christian Cabrol, and Iradj Gandjbakhch,
9 *Nonpenetrating Clips for Coronary Anastomosis, Annals of Thoracic Surgery*, Vol. 63
10 (1997) p. S137. (This article will hereinafter be referred to as “*Nonpenetrating Clips for*
11 *Coronary Anastomosis*”). Furthermore, it is considered that “suture anastomosis of small
12 vessels is time-consuming and tedious and demands a long and continuous training if
13 high patency rates are to be regularly achieved.” Willy D. Boeckx, Oliskevigius Darius,
14 Bert van den hof, and Carlo van Holder, *Scanning Electron Microscopic Analysis of the*
15 *Stapled Microvascular Anastomosis in the Rabbit, Annals of Thoracic Surgery*, Vol. 63
16 (1997) p. S128. (This work will hereinafter be referred to as “*Microscopic Analysis of*
17 *Stapled Microvascular Anastomosis*”). In contrast, in all specialties that employ vascular
18 surgery, “there is an increasing demand for a simple, time-saving, but reliable automated,
19 semiautomated, or at least facilitated method to replace the process of manually sutured
20 anastomosis. The most important reason for this demand is the movement of cardiac
21 bypass surgery toward a minimally invasive and possibly even an endoscopic procedure.”
22 *Review of Facilitated Approaches to Vascular Anastomosis*, p. S122. In this respect,
23 improvement “may come from techniques that do not lead to exposure of [a] damaged
24 vessel wall to the bloodstream.” *Id.*, p. S122.

25 Besides the group that includes techniques which rely on suturing, vascular
26 anastomosis techniques can generally be classified in four groups depending on how the

1 tissue is joined and on the type of device or material used for joining the tissue of the
2 anastomosed vessels. These groups are: Stapling and clipping techniques, coupling
3 techniques, pasting techniques, and laser techniques. *Id.*, pp. S122-S127.

4 **2.2.1. Stapling and clipping techniques**

5 Although some staplers have been reported as providing leaky joints, a variety of
6 staplers have been developed for end-to-end and for end-to-side anastomosis. U.S. Pat.
7 No. 5,366,462 discloses a method of end-to-side vascular anastomosis. According to this
8 method, the end of the graft blood vessel that is to be anastomosed is everted by 180°;
9 one end of the staple pierces both vessels with punctures exposed to the blood flow and
10 the other end of the staple pierces the outside of the receiving vessel. U.S. Pat. No.
11 5,732,872 discloses a surgical stapling instrument that comprises an expandable anvil for
12 aiding in the stapling of a 180° everted end of a graft vessel to a receiving vessel. This
13 patent also discloses a stapling instrument for joining the 180° everted second end of a
14 graft vessel whose opposite end has already been anastomosed. To anastomose this
15 second end, this technique requires clearance around the area in which the anastomosis is
16 performed, exposure of the receiving blood vessel, external anatomic identification, and
17 significant external manipulation in the open area around the anastomosis site. U.S. Pat.
18 No. 4,930,674 discloses methods of end-to-end and end-to-side anastomosis and a
19 surgical stapler that comprises a vessel gripping structure for joining the 180° everted end
20 of a graft vessel to another vessel. U.S. Pat. No. 5,695,504 discloses methods and a
21 system for performing an end-to-side vascular anastomosis, where the system is
22 applicable for performing an anastomosis between a vascular graft and the ascending
23 aorta in coronary artery bypass surgery, particularly in port-access coronary artery bypass
24 graft surgery. This system includes a staple with a configuration that combines the
25 functions of an anchor member and a coupling member into a one-piece anastomosis
26 staple. U.S. Pat. No. 5,861,005 discloses an arterial stapling method and device for

1 stapling an opening in an anatomical structure, whether the opening is deliberately
2 formed or accidentally caused. This device employs a balloon catheter that helps
3 positioning the stapling mechanism properly on the organ to be stapled.

4 Some stapling devices rely on access to the anastomosis area through an
5 opening that might be as big as or comparable to typical openings that are required in
6 surgical procedures. Furthermore, the 180° eversion of vessel ends is viewed as an
7 operation that can be difficult, particularly in sclerotic vessels. *Review of Facilitated*
8 *Approaches to Vascular Anastomosis*, p. S123.

9 In general, clipping techniques rely on arcuate legged clips for achieving a
10 flanged, nonpenetrated, intimal approximation of the anastomosed structures.
11 Reportedly, the use of clips leads to a biologically and technically superior anastomosis
12 as compared to the penetrating microsuture. *Review of Facilitated Approaches to*
13 *Vascular Anastomosis*, p. S123. By approximating the everted walls of the two vessels to
14 be anastomosed, a clipping technique avoids stitching and reportedly the subsequent risk
15 of intimal hyperplasia. Gianfranco Lisi, Louis P. Perrault, Philippe Menasché, Alain Bel,
16 Michel Wassef, Jean-Paul Vilaine, and Paul M. Vanhoutte, *Nonpenetrating Stapling: A*
17 *Valuable Alternative to Coronary Anastomoses*, *Annals of Thoracic Surgery*, Vol. 66
18 (1998) p. 1707. In addition, maintenance of an uninjured endothelial coverage and
19 avoidance of exposure of subintimal connective tissue are considered important features
20 because “regenerated endothelium presents selective dysfunction that may predispose to
21 spasm and atherosclerosis, thereby affecting both medium-term and long-term graft
22 patency” and the risk of thrombosis at the anastomotic site can be reduced. *Id.*, p. 1707.

23 Nonpenetrating vascular closure staples (“VCS”) have been used in anastomoses
24 performed to provide access for dialysis, as well as in kidney and pancreas
25 transplantation. It has been concluded in light of these anastomoses that “the fact that
26 VCS staples are interrupted and do not disrupt the endothelium or have an intraluminal

component makes them ideal” for achieving the goals of kidney transplantation. V.E. Papalois, J. Romagnoli, and N.S. Hakim, *Use of Vascular Closure Staples in Vascular Access for Dialysis, Kidney and Pancreas Transplantation, International surgery*, Vol. 83 (1998) p. 180. These goals include the avoidance of post-operative thrombosis and the avoidance of renal artery stenosis. As with kidney transplants, no anastomotic abnormalities were detected in pancreatic transplants, where the avoidance of arterial stenosis is also very important. *Id.*, p. 180. The results of anastomoses performed for providing vascular access for dialysis were also reported successful. *Id.*, p. 179. In addition, it has been reported that the “VCS applier is easy to manipulate, is as safe as hand-suture methods, and has time saving potential. VCS clips are useful for vascular anastomoses of blood access.” Hiroaki Haruguchi, Yoshihiko Nakagawa, Yasuko Uchida, Junichiro Sageshima, Shohei Fuchinoue and Tetsuzo Agishi, *Clinical Application of Vascular Closure Staple Clips for Blood Access Surgery, ASAIO Journal*, Vol. 44(5) (1998) pp. M562-M564.

In a study of microvascular anastomosis of rabbit carotid arteries, some anastomosis were stapled using non-penetrating 0.9 mm microclips and some anastomosis were conventionally sutured. Arcuate-legged, nonpenetrating titanium clips are applied according to a clipping technique in an interrupted fashion to everted tissue edges at high compressive forces. It is considered that this technique “enables rapid and precise microvascular reconstructions, but requires both training and evertable tissue walls.” *Nonpenetrating Clips for Coronary Anastomosis, Annals of Thoracic Surgery*, p. S135. An example of this clip applier is the VCS device, Autosuture, United States Surgical Corporation, Norwalk, Connecticut. *Nonpenetrating Clips for Coronary Anastomosis*, pp. S135-S137. U.S. Pat. No. 5,702,412 discloses a method and devices for performing end-to-side anastomoses where the side wall of one of the structures is cut

1 from the intraluminal space of the graft vessel and the anastomosed structures can be
2 secured by a plurality of clips or by suturing.

3 It has been concluded that stapled microvascular anastomosis is fast and reliable
4 and histomorphologic examination of the anastomotic site revealed no major differences
5 between sutured and stapled groups. *Microscopic Analysis of Stapled Microvascular*
6 *Anastomosis*, p. S128. Furthermore, it has also been reported that the “clipped
7 anastomotic technique has a rapid learning curve, the same safety as suture methods, and
8 the potential for facilitating endoscopic vascular reconstruction.” *Nonpenetrating Clips*
9 *for Coronary Anastomosis*, p. S135. In a study undertaken to compare VCS clips with
10 sutured arterial end-to-end anastomosis in larger vessels, it was concluded that this type
11 of anastomosis “can be performed more rapidly with VCS clips than continuous sutures”,
12 and that VCS clips “are potentially useful situations where the clamp time of the vessel is
13 critical.” Emmanouil Pikoulis, David Burris, Peter Rhee, Toshiya Nishibe, Ari
14 Leppäniemi, David Wherry and Norman Rich, *Rapid Arterial Anastomosis with Titanium*
15 *Clips, The American Journal of Surgery*, Vol. 175 (1998) pp. 494-496.

16 Nevertheless, clipping may lead to irregularities at the junction of the
17 anastomosed vessels. In addition, it has been reported that “both periadventitial tissue
18 stripping and microvascular clip application have deleterious effects in the early
19 postoperative period” and that “temporary clips with a lesser width must be used in place
20 of microvascular clips” while performing microvascular anastomosis. S. Keskil, N.
21 Çeviker, K. Baykaner, Ö. Uluoğlu and Z.S. Ercan, *Early Phase Alterations in*
22 *Endothelium Dependent Vasorelaxation Responses Due to Aneurysm Clip Application*
23 *and Related Manipulations, Acta Neurochirurgica*, Vol. 139(1) (1997) pp. 71-76.

24 2.2.2. Coupling

25 Tissue bonding by coupling with the aid of devices such as stents, ferrules, or
26 rings without staples is considered to be older than stapling. Among the more recent

1 devices and techniques, U.S. Pat. No. 4,523,592 discloses anastomotic coupling means
2 capable of end-to-end and end-to-side anastomosis without resorting to suturing. The
3 vessels are coupled with a pair of coupling disc members that cooperatively lock and
4 secure the everted tissue from the anastomosed structures. These everted tissues remain
5 in intima-intima contact with no foreign material exposed to the lumen of the
6 anastomosed vessels. U.S. Pat. Nos. 4,607,637, 4,917,090 and 4,917,091 also disclose
7 the use of anastomosis rings and an instrument for joining vessels or tubular organs
8 which are threaded to the annular devices before the joining. The instrument and the
9 anastomosis rings are shaped and adapted to be utilized mainly in microsurgery. U.S.
10 Pat. Nos. 4,657,019 and 4,917,087 disclose devices, kits and methods for non-suture end-
11 to-end and end-to-side anastomosis of tubular tissue members that employ tubular
12 connection members and provide intima-intima contact at the anastomosis site with no
13 foreign material exposed to the lumen of the vessels being joined. An annuli pair that
14 provides an anastomotic clamp and that is especially adapted for intraluminal disposition
15 is disclosed in U.S. Pat. No. 5,336,233. Because of the intraluminal disposition, this
16 device is exposed to the blood flow in the anastomosed vessels. U.S. Pat. No. 4,907,591
17 discloses a surgical instrument for use in the installation of an assembly of interlocking
18 coupling members to achieve compression anastomosis of tubular structures. Other
19 coupling devices include the use of intraluminal soluble stents and extraluminal glues,
20 such as cyanoacrylates, for creating nonsuture anastomoses. Reportedly, 98% patency
21 was obtained with these soluble polyvinyl alcohol stents. *Review of Facilitated*
22 *Approaches to Vascular Anastomosis*, pp. S124-S125. An absorbable anastomotic device
23 for microvascular surgery relies on the cuffing principle with injection-molding
24 techniques using the polymer polyglactin. Vessel ends that are everted 180° are joined in
25 this technique by an interconnecting collar so that an intima-intima seal is achieved.
26

Reportedly, 96% patency was obtained with these absorbable interconnecting collars.
1 *Review of Facilitated Approaches to Vascular Anastomosis*, p. S125.

2 The major advantage of a coupling microvascular anastomotic device has been
3 reported to be the reduction in the time needed for a venous anastomosis, which
4 decreases the total ischemic time. Maisie L. Shindo, Peter D. Constantino, Vincent P.
5 Nalbone, Dale H. Rice and Uttam K. Sinha, *Use of a Mechanical Microvascular*
6 *Anastomotic Device in Head and Neck Free Tissue Transfer*, *Archives of Otolaryngology*
7 *- Head & Neck Surgery*, Vol. 122(5) (1996) pp. 529-532. Although a number of coupling
8 techniques do not place any foreign body in the intraluminal space of the anastomosed
9 vessels, it is considered that the use of a foreign rigid body such as a ring that encloses a
10 dynamically dilating structure is a disadvantage of this type of technique. Furthermore,
11 this type of technique is viewed as not being flexible enough for its application to
12 significant vessel size discrepancies in end-to-side anastomosis, and the devices are
13 characterized as being of limited availability and needed in sets of different sizes.
14 *Microscopic Analysis of Stapled Microvascular Anastomosis*, p. S128. In addition, most
15 coupling techniques require considerable eversion, incisions and mounting of the
16 coupling devices that are difficult or impossible to apply endoscopically.

17 18 **2.2.3. Adhesives**

19 Pasting by applying adhesives or glues is widely employed in medicine. Several
20 glues have been tested in anastomotic procedures, including fibrin glue, cyanoacrylic
21 glues and photopolymerizable glues.

22 Fibrin glue is a biological two-component sealant comprising fibrinogen solution
23 and thrombin combined with calcium chloride solution. These components are typically
24 available deep-frozen in preloaded syringes, and they are mixed during application after
25 thawing. Commercially available fibrin glue Tissucol has reportedly been approved by
26

1 the Food and Drug Administration for use in the United States. See, Thomas Menovsky
2 and Joost de Vries, *Use of Fibrin Glue to Protect Tissue During CO₂ Laser Surgery*,
3 *Laryngoscope* Vol. 108 (1998) pp. 1390-1393. This article will hereinafter be referred to
4 as "*Fibrin Glue in Laser Surgery*."

5 The use of fibrin glue has been found to be practical in telescoping anastomoses
6 and in microanastomoses. Satoru Saitoh and Yukio Nakatsuchi, *Telescoping and Glue*
7 *Technique in Vein Grafts for Arterial Defects, Plastic and Reconstructive Surgery*, Vol.
8 96(6) (1995) pp. 1401-1408; Seung-Kyu Han, Sung-Wook Kim and Woo-Kyung Kim,
9 *Microvascular Anastomosis With Minimal Suture and Fibrin Glue: Experimental and*
10 *Clinical Study, Microsurgery*, Vol. 18(5) (1998) pp. 306-311. In contrast, it has been
11 reported that the application of thrombin-based fibrin sealant (fibrin glue) to
12 microvascular anastomoses can have noticeable deleterious effects, particularly when
13 used in venous anastomosis. Christopher A. Marek, Lester R. Amiss, Raymond F.
14 Morgan, William D. Spotnitz and David B. Drake, *Acute Thrombogenic Effects of Fibrin*
15 *Sealant on Microvascular Anastomoses in a Rat Model, Annals of Plastic Surgery*, Vol.
16 41(4) (1998) pp. 415-419.

17 A biological procoagulant solution has been described as promising. The
18 mixture contains bovine microfibrillar collagen and thrombin. Gary Gershony, John M.
19 Brock and Jerry S. Powell, *Novel Vascular Sealing Device for Closure of Percutaneous*
20 *Vascular Access Sites, Catheterization and Cardiovascular Diagnosis*, Vol. 45(1) (1998)
21 pp. 82-88; Ted Feldman, *Percutaneous vascular Closure: Plugs, Stitches, and Glue*,
22 *Catheterization and Cardiovascular Diagnosis*, Vol. 45(1) (1998) p. 89; Zoltan G. Turi,
23 *Plugging the Artery With a Suspension: A Cautious Appraisal, Catheterization and*
24 *Cardiovascular Diagnosis*, Vol. 45(1) (1998) pp. 90-91.

25 Cyanoacrylic glues tested on vessels include methyl cyanoacrylate and butyl
26 cyanoacrylate, such as Histoacryl glue (butyl-2-cyanoacrylate). The ultra-violet

polymerizable glue polyethyleneglycol 400 diacrylate has also been tested and reported that it "is able to effectively seal vessel puncture sites and anastomotic junctions without acutely augmenting local vascular thrombogenicity." G.A. Dumanian, W. Dascombe, C. Hong, K. Labadie, K. Garrett, A.S. Sawhney, C.P. Pathak, J.A. Hubbell and P.C. Johnson, *A new Photopolymerizable Blood Vessel Glue That Seals Human Vessel Anastomoses Without Augmenting Thrombogenicity, Plastic and Reconstructive Surgery*, Vol. 95(5) (1995) pp. 901-907.

Glues used in anastomotic practice face the challenges inherent to factors that include toxicity, thrombogenicity, vascular wall thinning, and mechanical strength of the joint. *Review of Facilitated Approaches to Vascular Anastomosis*, p. S125; Henk Giele, *Histoacryl Glue as a Hemostatic Agent in Microvascular Anastomoses, Plastic and Reconstructive Surgery*, Vol. 94(6) (1994) p. 897.

2.2.4. Lasers

Lasers have been used in angioplastic revascularization since about 1984. See for example, Markolf H. Niemz, *Laser Tissue Interactions*, pp. 216-221, Springer Verlag 1996, (this work will hereinafter be referred to as "*Laser Tissue Interactions*"); R. Viligiardi, V. Gallucci, R. Pini, R. Salimbeni and S. Galiberti, *Excimer Laser Angioplasty in Human Artery Disease*, in *Laser Systems in Photobiology and Photomedicine*, edited by A.N. Chester, S. Martellucci and A.M. Scheggi, pp. 69-72, Plenum Press, New York, 1991; Timothy A. Sanborn, *Laser Angioplasty*, in *Vascular Medicine*, edited by Joseph Loscalzo, Mark A. Creager and Victor Brounwald, pp. 771-787, Little Brown Co. Whereas balloon angioplasty typically fractures, compresses or displaces plaque material, laser angioplasty typically removes plaque material by vaporizing it. Lawrence I. Deckelbaum, *Cardiovascular Applications of Laser Technology*, in *Laser Surgery and Medicine*, edited by Carmen A. Puliafito, pp. 1-27, Wiley-Liss, 1996.

1 The refinement of anastomosis techniques that rely on laser has been progressing
2 since the reportedly first use of a neodymium yttrium-aluminum-garnet laser ("Nd-YAG
3 laser") on vascular anastomosis in 1979. Particularly in an end-to-side vascular
4 anastomosis, the end of a graft in the form of a tubular structure is connected to the side
5 wall of a receiving vessel so that the anastomosed end of the graft encompasses the
6 anastomosis fenestra, or artificial window, that has been formed into the side wall of the
7 receiving vessel. Consequently, lasers can be used in anastomoses for welding the
8 anastomosed structures and/or for opening the anastomosis fenestra. In addition to YAG
9 lasers, such as Nd-YAG and Ho-YAG lasers, Excimer, diode, CO₂, and argon lasers have
10 also been used in vascular anastomoses.

11 Laser welding has been defined as the process of using laser energy to join or
12 bond tissues. Typically, laser welding relies on photothermal effects, but efforts are
13 being made to develop laser welding that relies on photochemical effects, where the laser
14 radiation activates cross-linking agents that are expected to produce stronger links than
15 those produced by photothermal welding. Lawrence S. Bass and Michael R. Treat,
16 *Laser Tissue Welding: A Comprehensive Review of Current and Future Clinical*
17 *Applications*, in *Laser Surgery and Medicine*, edited by Carmen A. Puliafito, pp. 381-
18 415. (This work will hereinafter be referred to as "*Laser Tissue Welding*").

19 Generally, the use of lasers in anastomotic practice faces the challenges inherent
20 to factors that include the cost of laser purchase, maintenance and training, radiation
21 damage to surrounding tissue, aneurism formation, the need for about three or four
22 sutures (versus the nine or ten sutures applied in conventional anastomosis), side effects
23 of heat-induced tissue welding, and mechanical failure at the anastomosis site. *Review of*
24 *Facilitated Approaches to Vascular Anastomosis*, pp. S125-S126; *Laser Tissue Welding*,
25 pp. 407-410; Brian C. Cooley, *Heat-Induced Tissue Fusion For Microvascular*
26 *Anastomosis, Microsurgery*, Vol 17(4) (1996) pp. 198-208. It has been reported,

1 however, that the “nonocclusive Excimer laser-assisted anastomosis technique is safe and
2 yields a high long-term patency rate in neurosurgical patients” and that there might be
3 indications for this method in coronary bypass surgery. Cornelis A.F. Tulleken, Rudolf
4 M. Verdaasdonk, and Hendricus J. Mansvelt Beck, *Nonocclusive Excimer Laser-Assisted*
5 *End-to-Side Anastomosis*, *Annals of Thoracic Surgery*, Vol. 63 (1997) pp. S138-S142.
6 (This article will hereinafter be referred to as “*Nonocclusive Excimer Laser-Assisted End-*
7 *to-Side Anastomosis*”). In addition, laser anastomosis is considered to offer moderately
8 reduced operative time, reduced skill requirements, faster healing, ability to grow, and
9 possibly reduced intimal hyperplasia. *Laser Tissue Welding*, pp. 407-410 (further
10 reporting on selected microvascular anastomosis studies with lasers that include CO₂,
11 argon, and diode lasers). Furthermore, research is being done to replace some of the
12 initial laser sources by other lasers that are believed to be more suitable for clinical
13 applications. For example, recent work with the 980 nm diode laser indicates that it may
14 “replace in the near future laser sources of older conception such as the Nd-YAG.” W.
15 Cecchetti, S. Guazzieri, A. Tasca and S. Martellucci, *980 nm High Power Diode Laser in*
16 *Surgical Applications*, in *Biomedical Optical Instrumentation and Laser-Assisted*
17 *Biotechnology*, edited by A.M. Verga Scheggi, S. Martellucci, A.N. Chester and R.
18 Pratesi, pp. 227-230, Kluwer Academic Publishers, Dordrecht, The Netherlands, 1996.

19 The CO₂ laser can seal blood vessels, including small blood vessels of about 0.5
20 mm in diameter or less and it has been used in microvascular anastomosis such as in
21 human lympho-venous anastomosis. D.C. Dumitras and D.C.A. Dutu, *Surgical*
22 *Properties and Applications of Sealed-off CO₂ Lasers*, in *Biomedical Optical*
23 *Instrumentation and Laser-Assisted Biotechnology*, edited by A.M. Verga Scheggi, S.
24 Martellucci, A.N. Chester and R. Pratesi, pp. 231-239, Kluwer Academic Publishers,
25 Dordrecht, The Netherlands, 1996. In addition to the CO₂ laser which is an efficient
26

1 vaporizer of tissue, other lasers that effectively vaporize tissue include the argon and the
2 KTP/532 lasers. *Lasers - Invention to Application*, p. 106.

3 The argon laser has been reported to offer advantages over conventional end-to-
4 end anastomosis procedures applied to growing vessels. Eiji Chikamatsu, Tsunehisa
5 Sakurai, Naomichi Nishikimi, Takashi Yano and Yuji Nimura, *Comparison of Laser*
6 *Vascular Welding, Interrupted Sutures, and Continuous Sutures in Growing Vascular*
7 *Anastomoses, Lasers in Surgery and Medicine*, Vol. 16(1) (1995) pp. 34-40. It has also
8 been reported that low temperature argon laser welding limits anastomotic
9 thrombogenicity, which is thought of as a factor that may improve early patency of
10 venous and small arterial bypass grafts. Steven B. Self, Douglas A. Coe and James M.
11 Seeger, *Limited Thrombogenicity of Low Temperature Laser-Welded Vascular*
12 *Anastomoses, Lasers in Surgery and Medicine*, Vol. 18(3) (1996) pp. 241-247.

13 The use of laser for medical purposes requires safety measures for protecting
14 health care practitioners who handle the laser device and for shielding surrounding tissues
15 and avoiding unintended radiation induced damage. Laser shield materials include layers
16 of polymethylmethacrylate and tinfoil. See, Christine C. Nelson, Krystyna A. Pasyk and
17 Gregory L. Dootz, *Eye Shield for Patients Undergoing Laser Treatment, American*
18 *Journal of Ophthalmology* Vol. 110 (1990) pp. 39-43. Laser shield materials are known
19 and they have been disclosed in a variety of sources such as Alex Mallow and Leon
20 Chabot, *Laser Safety Handbook*, Van Nostrand Reinhold Co., New York (1978), and A.
21 Roy Henderson, *A Guide to Laser Safety*, Chapman & Hall, London (1997). In
22 particular, for example, the biological sealant fibrin glue can prevent severe damage to
23 tissue when accidentally exposed to CO₂ laser radiation and intraoperative coating with
24 fibrin glue can serve as a shield to protect arteries, veins, and nerves from accidental CO₂
25 laser exposure. Furthermore, it is considered that the use of fibrin glue for laser radiation
26

1 protective processes "is especially attractive in ... fields in which the glue is already used
2 for sealing." *Fibrin Glue in Laser Surgery* at p. 1393.

3 **2.2.5. Other devices and techniques**

4 It is known that some anastomosis techniques combine different approaches. For
5 example, biological glues that are based on proteins and other compounds are combined
6 with laser radiation in laser soldering. "Laser soldering is a bonding technique in which a
7 proteinaceous solder material is applied to the surfaces to be joined followed by
8 application of laser light to seal the solder to the tissue surfaces." *Laser Tissue Welding*,
9 pp. 389-392. Egg albumin, heterologous fibrin glue, and human albumin have been used
10 as laser solders, also known as adjuvant materials for laser tissue welding. Dix P.
11 Poppas, Theodore J. Choma, Christopher T. Rooke, Scott D. Klioze and Steven M.
12 Schlossberg, *Preparation of Human Albumin Solder for Laser Tissue Welding, Lasers in*
13 *Surgery and Medicine*, Vol. 13(5) (1993) pp. 577-580.

14 In an even newer technique, a chromophore is added to the solder to achieve
15 photoenhancement effects that lead to an enhanced light absorption in the solder and not
16 in the nontargeted tissue. *Id.*, p. 391. In laser sealing, also known as laser-activated
17 tissue sealing, sutured or stapled repairs are reinforced with laser solder, which is
18 expected to provide "the strength and security of sutures and the watertightness of
19 solder." *Id.*, pp. 403-404.

20 The graft in a vascular anastomosis does not necessarily have to be an
21 autologous blood vessel. In addition to ePTFE tubular grafts that have been referred to in
22 a preceding subsection, several synthetic materials for vascular grafts have been used or
23 are being developed.

1 Synthetic biomaterials that are being developed include polymeric materials
2 with the proteins elastin and fibronectin. A. Maureen Rouhi, *Contemporary*
3 *Biomaterials, Chemical & Engineering News*, Vol. 77(3) (1999) pp. 51-63.

4 ePTFE has been used with a variety of coatings. One type of coating includes
5 fibrin glue that contains fibroblast growth factor type 1 and heparin. John L. Gray,
6 Steven S. Kang, Gregory C. Zenni, Dae Un Kim, Petre I. Kim, Wilson H. Burgess,
7 William Drohan, Jeffrey A. Winkels, Christian C. Haudenschild and Howard P. Greisler,
8 *FGF-1 Affixation Stimulates ePTFE Endothelialization without Intimal Hyperplasia*,
9 *Journal of Surgical Research*, Vol. 57(5) (1994) pp. 596-612; Joseph I. Zarge, Vicki
10 Husak, Peter Huang and Howard P. Greisler, *Fibrin Glue Containing Fibroblast Growth*
11 *Factor Type 1 and Heparin Decreases Platelet Deposition*, *The American Journal of*
12 *Surgery*, Vol. 174(2) (1997) pp. 188-192; Howard P. Greisler, Claire Gosselin, Dewei
13 Ren, Steven S. Kang and Dae Un Kim, *Biointeractive Polymers and Tissue Engineered*
14 *Blood Vessels*, *Biomaterials*, Vol. 17(3) (1996) pp. 329-336. Another coating contains
15 basic fibroblast growth factor in fibrin glue. M. Lanzetta, D.M. Crowe and M.J. Hickey,
16 *Fibroblast Growth Factor Pretreatment of 1-mm PTFE Grafts*, *Microsurgery*, Vol.
17 17(11) (1996) pp. 606-611.

18 Other grafts comprise a synthetic biodegradable tubular scaffold, such as a vessel
19 made of polyglactin/polyglycolic acid, that has been coated with autologous cells from a
20 tissue culture. Toshiharu Shinoka, Dominique Shum-Tim, Peter X. Ma, Ronn E. Tanel,
21 Noritaka Isogai, Robert Langer, Joseph P. Vacanti and John E. Mayer, Jr., *Creation of*
22 *Viable Pulmonary Artery Autografts Through Tissue Engineering*, *The Journal of*
23 *Thoracic and Cardiovascular Surgery*, Vol. 115(3) (1998) pp. 536-546.

24 A common feature of most conventional stapling, coupling and clipping
25 techniques, particularly when applied to small-diameter vessels, is that they require a
26 temporary interruption of the blood stream in the recipient vessel, a disruption that is

1 thought to be not very well tolerated in cardiac bypass surgery. *Review of Facilitated*
2 *Approaches to Vascular Anastomosis*, p. S126. In revascularization procedures of the
3 brain, temporary occlusion of a proximal brain artery may cause brain ischemia, and
4 consequently a nonocclusive anastomosis technique is required. *Nonocclusive Excimer*
5 *Laser-Assisted End-to-Side Anastomosis*, p. 141. As the instrumentation that is needed at
6 the anastomosis site becomes complex and cumbersome, a wider open area is needed for
7 accessing the anastomosis site, thus leading to an increasingly invasive procedure.
8 Furthermore, conventional anastomosis techniques are usually performed at a site that is
9 determined by external observation of the affected area. This observation is performed at
10 a time and in a medical setup that are different from the time and medical setup of a
11 previous exploratory or diagnosis procedure.

12 Techniques that require the perforation of blood vessel tissue have raised
13 concerns regarding intimal injury, adventitial stripping, tissue plane malalignment, and
14 anastomotic bleeding. In addition, techniques that rely on devices that are exposed to the
15 blood flow may lead to technical problems associated with a persistent intraluminal
16 foreign body. These factors are thought to "contribute to both early and late anastomotic
17 failure, particularly in the form of neointimal hyperplasia." *Nonpenetrating Clips for*
18 *Coronary Anastomosis*, p. S135.

19 The need for completely endoscopic anastomosis procedures has been clearly
20 expressed in the context of coronary artery bypass grafting. For example, it is currently
21 acknowledged that "the goal of a completely endoscopic coronary artery bypass
22 procedure has not yet been realized, and will require further technological advances."
23 *Endoscopic Coronary Artery Bypass Grafting*, p. 1064. Furthermore, totally endoscopic
24 coronary artery bypass grafting "is perceived by many as the ultimate surgical model of
25 minimally invasive coronary artery bypass grafting". Hani Shennib, Amr Bastawisy,
26 Michael J. Mack, and Frederic H. Moll, *Computer-Assisted Telem Manipulation: An*

1 *Enabling Technology for Endoscopic Coronary Artery Bypass, Annals of Thoracic*
2 *Surgery*, Vol. 66 (1998) p. 1060.

3 Minimally invasive vascular grafting according to a peripheral procedure is
4 equally desirable, and minimally invasive active endoscopic or peripheral methods,
5 systems and devices are specially desirable. In addition, methods, systems and devices
6 that can be used in catheter directed as well as in non-catheter directed vascular
7 anastomosis are particularly desirable because sometimes an occluded or damaged vessel
8 does not permit catheterization from a point that is too far from the anastomosis site.

9 These methods, systems and apparatuses are specially desirable when, in
10 particular, they are versatile enough as to be able to incorporate a plurality of the
11 desirable features that have been discussed hereinabove while reviewing different groups
12 of vascular anastomosis techniques. This desirability is consistent with the reported
13 expectation that reliable methods for facilitated anastomosing of vessels will be
14 developed by combining the best features of a variety of techniques. *Review of*
15 *Facilitated Approaches to Vascular Anastomosis*, p. S126.

16 Each one of the afore-mentioned patents and publications is hereby incorporated
17 by reference in its entirety for the material disclosed therein.

OBJECTS AND BRIEF SUMMARY OF THE INVENTION

1 Conventional anastomosis techniques do not rely on intraluminally directed
2 anastomosis procedure. It is therefore desirable to provide methods, systems and devices
3 for achieving intraluminally directed anastomosis.

4 An object of the present invention is to provide apparatus, methods, systems for
5 performing an anastomosis through use of an intraluminally directed anvil apparatus or
6 alternatively an externally positioned anvil apparatus.

7 Another object of this invention is to provide systems and apparatus that work in
8 conjunction with an intraluminally directed anvil apparatus to anastomose vessels
9 together.

10 Additionally, another object of this invention is to provide methods, systems, and
11 devices for joining vessels together in a secure manner such that the portions defining the
12 openings of the vessels are not penetrated.

13 Additionally, another object of this invention is to provide methods, systems, and
14 devices for joining vessels together through the use of plates that are guided to each other
15 by guides.

16 Still another object of the present invention is to provide methods, systems, and
17 devices that are versatile enough to be able to suitably combine a variety of cutting,
18 welding, and joining techniques in the practice of vascular anastomosis.

19 A feature of this invention is that the anvil apparatus can be positioned in a
20 vessel intraluminally such that an anvil abuts the wall of the vessel with an anvil pull
21 extending through an initial piercing in the vessel wall. This is preferably achieved
22 through the use of a catheter inserted into and along the intraluminal space of a receiving
23 blood vessel. Because the initial piercing is too small for the anvil to pass through, the
24 anvil pull can be pulled in a manner that causes the wall of the vessel to be distended.
25
26

1 The opening is formed in a manner that consistently creates a complete cut
2 having a perimeter with a desired shape such as a circle or an ellipse depending on the
3 type of anastomosis. The precision of the cutting is due to several features. As
4 mentioned above, the vessel wall is distended over the anvil which enables the wall to be
5 stretched. This assists in creating a clean cut. The anvil is larger than the cutter so that
6 the cut is formed due to the pressure between anvil and the cutter instead of forcing the
7 vessel between the cutter and the anvil. Also, the anvil is preferably configured such that
8 it has an engaging end that is convex and is more preferably spherical so that when
9 engaged by a cylindrical cutter the cutter can self center on the engaging end. The cutter
10 is also preferably spring biased which provides increased pressure for engaging the anvil.

11 The ability to distend the vessel wall is particularly useful when a compression
12 plate apparatus is utilized to join the vessels. This compression plate apparatus includes
13 two opposing and generally annular compression plates in a generally coaxial orientation.
14 The end of the graft vessel that is to be anastomosed is everted onto one of the
15 compression plates. The anvil pull is used to distend the receiving vessel wall such that it
16 extends into compression plate apparatus. With the other compression plate placed at and
17 around the anastomosis site, an anastomosis fenestra is opened in the wall of the
18 receiving vessel. This anastomosis fenestra is opened within the annular region generally
19 defined by the compression plate located at and around the anastomosis site. With the aid
20 of the anvil of this invention, the contour of the anastomosed fenestra is engaged with the
21 compression plate which opposes the compression plate that carries the graft vessel. This
22 engagement is preferably accomplished with the aid of holding tabs protruding from the
23 compression plate placed around the anastomosis fenestra. The degree to which the anvil
24 has distended the receiving vessel before formation of the fenestra determines the size of
25 the portion defining the vessel opening that remains in the compression plate apparatus.
26 By adequately distending the receiving vessel wall, the portion defining the opening can

1 be captured by the compression plate apparatus and everted. The graft vessel is
2 subsequently approached to the anastomosis fenestra by reducing the separation between
3 the compression plates, so that the graft vessel causes the eversion of the contour of the
4 anastomosis fenestra by appropriately sliding on the surface of the anvil. Once the
5 portion of the vessel that defines the opening has been everted then the compression plate
6 apparatus can be compressed in a manner such that the everted portion of the receiving
7 vessel is held against the everted portion of the other vessel such as a graft vessel. The
8 relative separation of the compression plates is reduced to the extent necessary to bring
9 the everted edges of the anastomosed structures into contact engagement so that a leak
10 proof anastomosis is achieved.

11 A feature of the present invention is that the compression plate apparatus is
12 suitable for end-to-side anastomosis in addition to side-to-side anastomosis.
13 Furthermore, the compression plate apparatus of this invention provides support to the
14 anastomosed structures in a manner such that the compression plates do not disrupt the
15 periodic dilation of the anastomosed structures as is required by the characteristics of the
16 blood flow that circulates therethrough. Moreover, the compression plate apparatus of
17 this invention is used, together with the anvil, to evert the contour of the anastomosed
18 fenestra in the receiving vessel while the anastomosis takes place. In addition, the
19 compression plate apparatus of this invention can be used in conjunction with an anvil
20 and anvil pull, regardless of whether the vascular anvil and wire are introduced into the
21 receiving blood vessel with the aid of a catheter or directly into the intraluminal space
22 through a small incision at the anastomosis site.

23 Another feature of the present invention is that the anvil is configured in a way
24 such that it cooperates with the cutting element in the opening of the anastomosis fenestra
25 and it also cooperates with the compression plate apparatus in the eversion of the edge of
26 the anastomosed fenestra. By joining the everted contour of the anastomosis fenestra

1 with the everted edge of the graft vessel, significant exposure to the blood flow of the cut
2 portion of the anastomosed structures is avoided. Furthermore, the use of the anvil in a
3 plurality of operations permits a considerable simplification of the anastomosis
4 procedure. These operations include the abutting of the receiving blood vessel wall at the
5 anastomosis site, the opening of the anastomosis fenestra in the receiving blood vessel,
6 the eversion of edge of the anastomosis fenestra, and the joining of the anastomosed
7 structures.

8 As discussed in more detail hereinbelow, the opening of the anastomosis fenestra
9 can be performed mechanically or with the aid of a radiation-based device. The graft
10 vessel is joined to the wall of the receiving blood vessel by a compression plate device.
11 This device is configured in a manner such that it permits the use of supplementing
12 joining techniques and combinations thereof. These techniques include welding,
13 soldering, and gluing. Moreover, the signaling of the anastomosis site is preferably
14 performed with the aid of a mechanical device such as the combination of a wire and an
15 anvil.

16 The compression plate apparatus may be two opposing plates that are guided to
17 each other as they are compressed together by guides which ensure that the plates
18 maintain a parallel orientation with respect to each other. The compression plate
19 apparatus may also be a snap-fit apparatus which ensures that the vessels are held
20 together without penetrating the portions of the vessels that define the openings.

21 Many of the features obtained through the use of an intraluminally directed anvil
22 apparatus can also be utilized in conjunction with an externally positioned anvil
23 apparatus. For example, the advantageous cutting properties achieved with an
24 intraluminally positioned anvil apparatus engaging a cutter as described above can also
25 be used by an anvil apparatus that has been positioned within the lumen of a vessel by
26 inserting the anvil through an insertion opening in the vessel.

1 An external anastomosis operator is also provided that controls the anastomosis
2 procedure once the anvil pull extends out of the wall of the vessel and can be engaged.
3 The external anastomosis operator enables the anastomosis procedure to be mechanized so
4 that it is rapidly and reliably completed in a highly controlled manner. The external
5 anastomosis operator can also be utilized with an anvil apparatus that has been positioned
6 externally into a vessel as well as the compression plates.

7 One advantage of performing a minimally invasive anastomosis under the active
8 endoscopic or peripheral procedure that is based on the methods, systems, and devices of
9 the present invention is that its practice does not require the training in surgical methods
10 and techniques that the practice of surgery requires. Cross-specialty teams of
11 practitioners including those with training in endovascular intervention as well as
12 conventional surgical training can consequently perform minimally invasive anastomoses
13 according to the methods, apparatuses, and systems of this invention.

14 Another feature of the active endoscopic or peripheral procedure of this
15 invention is that it directly employs information while it is being acquired in an
16 angiographic examination. This efficient use of information, and in particular imaging,
17 has the advantage that the anastomosis is actually performed in less time and without
18 having to rely on the correlation of previously recorded images with external anatomic
19 inspection for locating the optimal anastomosis site. The shorter procedure according to
20 this invention consequently requires less or no hospitalization time and less medical
21 resources.

22 Still another feature of the active endoscopic or peripheral procedure of this
23 invention is that it requires no sutures. The avoidance of sutures has the advantages of
24 reducing the invasive character of the procedure, reducing the number of mechanical
25 elements in the practice of the anastomosis, and shortening the time needed to perform
26 the anastomosis.

1 By not requiring the interruption of blood flow in the receiving blood vessel, the
2 active endoscopic or peripheral procedure of this invention advantageously reduces or
3 even eliminates the risk of ischemia in organs that receive their main supply of blood
4 through the receiving blood vessel. Furthermore, the exposure of the anastomosis area is
5 reduced because no devices have to be introduced to temporarily interrupt blood flow.
6 This feature advantageously enhances the minimally invasive character of the methods,
7 systems, and apparatuses of this invention and the intervention time for the practice of the
8 anastomosis.

9 The minimal disruption of blood flow in the receiving blood vessel by the active
10 endoscopic or peripheral procedure of this invention advantageously makes it suitable in
11 the context of coronary artery bypass grafting (CABG), whether blood circulation is
12 intracorporeal or extracorporeal, and whether the grafting is performed on a beating heart
13 or an arrested heart.

14 A feature of the catheter assisted endoscopic or peripheral procedure of this
15 invention is the versatility of the vascular anvil and wire for signaling the anastomosis
16 site and of the extravascular device and cooperatively performing the anastomosis.
17 Accordingly, a variety of devices and techniques can be advantageously combined in the
18 context of this invention to enhance the performance of its methods, systems and devices.

19 These and other objects, features, and advantages of the present invention will
20 become more fully apparent from the following description and appended claims, or may
21 be learned by the practice of the invention as set forth hereinafter.
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23
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25
26

BRIEF DESCRIPTION OF THE DRAWINGS

1 In order that the manner in which the above-recited and other advantages and
2 objects of the invention are obtained, a more particular description of the invention
3 briefly described above will be rendered by reference to specific embodiments thereof
4 which are illustrated in the appended drawings. Understanding that these drawings depict
5 only typical embodiments of the invention and are not therefore to be considered to be
6 limiting of its scope, the invention will be described and explained with additional
7 specificity and detail through the use of the accompanying drawings in which:

8 FIG. 1 is a perspective view of a patient receiving a catheter at a catheterization
9 site as a guide wire is directed to a remote anastomosis site.

10 FIG. 2A is an enlarged partial cross-sectional view of a vessel with the coil of a
11 guide wire positioned at the selected anastomosis site.

12 FIG. 2B is an enlarged partial cross-sectional view of the vessel shown in FIG.
13 2A depicting the next phase of utilizing the catheter system after a positioning catheter is
14 positioned at the anastomosis site.

15 FIG. 2C is an enlarged partial cross-sectional view of the vessel shown in FIG.
16 2B depicting the next phase of utilizing the catheter system as the penetration catheter
17 and the penetration wire extending through an initial piercing at the anastomosis site.

18 FIG. 2D is an enlarged partial cross-sectional view of the vessel shown in FIG.
19 2C depicting the next phase of utilizing the catheter system after the penetration wire has
20 been removed so that only the penetration catheter remains.

21 FIG. 2E is an enlarged partial cross-sectional view of the vessel shown in FIG.
22 2D depicting the next phase of utilizing the catheter system as an anvil pull of an
23 intraluminally directed anvil apparatus is inserted through the penetration catheter.

24 FIG. 2F is an enlarged partial cross-sectional view of the vessel shown in FIG.
25 2E after the anvil pull of an intraluminally directed anvil apparatus has been pulled
26

1 through the wall of the vessel 20 so that the anvil is brought into contact with the interior
2 of the vessel.

3 FIG. 3A is a perspective view of a guided compression plate apparatus with
4 phantom lines to show the compressed position.

5 FIG. 3B is a perspective view of the guided compression plate apparatus shown
6 in FIG. 3A with a graft vessel loaded onto the holding tabs of the second compression
7 plate and a cutter positioned to be loaded into the lumen of the graft vessel.

8 FIG. 4A is a cross-sectional view of the compression plate apparatus shown in
9 FIG. 3A as anvil apparatus distends a blood vessel into the compression plate apparatus.

10 FIG. 4B is a cross-sectional view of the compression plate apparatus shown in
11 FIG. 4A in the next phase as a cutter and an anvil are engaged to form an opening in the
12 vessel.

13 FIG. 4C is a cross-sectional view of the compression plate apparatus shown in
14 FIG. 4B in the next phase after the second compression plate has been compressed
15 towards the first compression plate such that the everted graft vessel contacts the everted
16 blood vessel.

17 FIG. 4D is a cross-sectional view of the compression plate apparatus shown in
18 FIG. 4C with the anastomosed structure after the anvil apparatus and the cutter have been
19 removed.

20 FIG. 5A is a perspective view of the guided compression plate apparatus shown
21 in FIG. 3A with a graft vessel loaded onto the holding tabs of the second compression
22 plate, a cutter positioned in the lumen of the graft vessel and an adapter ready to be
23 positioned on the second compression plate.

24 FIG. 5B is a perspective view of the guided compression plate apparatus shown
25 in FIG. 3A with a graft vessel loaded onto the holding tabs of the second compression
26

1 plate, a cutter positioned in the lumen of the graft vessel and an adapter positioned on the
2 second compression plate.

3 FIG. 6A is a perspective view of an external anastomosis operator.

4 FIG. 6B is an exploded perspective view of the external anastomosis operator.

5 FIG. 6C is a cross-sectional view of the external anastomosis operator.

6 FIG. 6D is a cross-sectional view of the external anastomosis operator as the
7 anvil pull advancer knob is rotated to pull the anvil pull so that the anvil causes distension
8 of the blood vessel into the compression plate apparatus.

9 FIG. 6E is a cross-sectional view of the external anastomosis operator as the
10 attachment actuator device is moved to compress the second compression plate against
11 the first compression plate.

12 FIG. 7A is a perspective view of an alternative embodiment of an anvil having a
13 slightly tapered landing.

14 FIG. 7B is a perspective view of an alternative embodiment of an anvil having a
15 flared flange.

16 FIG. 7C is a perspective view of an alternative embodiment of an anvil having a
17 tapered terminal end.

18 FIG. 7D is a perspective view of an alternative embodiment of an anvil having
19 an elliptical engaging end and an eccentrically connected anvil pull.

20 FIG. 8 is an enlarged partial cross-sectional view of the vessel shown in FIG.
21 2A-2F depicting an anvil pull of an intraluminally directed anvil apparatus pulled through
22 the wall of the vessel 20 so that the anvil is brought into contact with the interior of the
23 vessel after the apparatus has been positioned by a positioning stem extending from the
24 anvil.

25 FIG. 9A is a perspective view of a mechanically expandable anvil.

26 FIG. 9B is a cross-sectional view of the anvil shown in Fig. 9A.

FIG. 10A is a perspective view of another mechanically expandable anvil.

FIG. 10B is a cross-sectional view of the anvil shown in Fig. 10A.

FIG. 11A is a perspective view of a chemically expandable anvil.

FIG. 11B is a cross-sectional view of the anvil shown in Fig. 11A.

FIG. 12A is a perspective view of a snap-fit compression plate apparatus.

FIG. 12B is a perspective view of the snap-fit compression plate apparatus shown in FIG. 12A with a graft vessel loaded onto the holding surface of the second compression plate.

FIG. 12C is a cross-sectional view of the compression plate apparatus shown in FIG. 12B as anvil apparatus distends a blood vessel into the compression plate apparatus.

FIG. 12D is a cross-sectional view of the compression plate apparatus shown in FIG. 12A in the next phase as a cutter and an anvil are engaged to form an opening in the vessel.

FIG. 12E is an enlarged partial cross-sectional view of the compression plate apparatus shown in FIG. 12D in the next phase as the graft vessel everts the portion of the blood vessel defining the first vessel opening.

FIG. 12F is a cross-sectional view of the compression plate apparatus shown in FIG. 12B in the next phase after the second compression plate has been compressed towards the first compression plate such that the everted graft vessel contacts the everted blood vessel.

FIG. 12G is a cross-sectional view of the compression plate apparatus shown in FIG. 12C with the anastomosed structure after the anvil apparatus and the cutter have been removed.

FIG. 13 is a perspective view of guided compression plate apparatus adapted for use in joining vessels at angles with elliptical openings with a graft vessel ready to be

received through a cutter and loaded onto the holding tabs of the second compression plate.

FIG. 14A is a perspective view of a cutter ready to engage an anvil with a thread anvil pull extending through the cutter to an anvil pull engager to form a circular opening.

FIG. 14B is a perspective view of a cutter ready to engage an anvil with a thread anvil pull extending through the cutter to an anvil pull engager to form an elliptical opening.

FIG. 14C is a perspective view of a clipping device applying clips to join two vessels in a nonperpendicular orientation.

FIG. 14D is a cross-sectional view of the device capable cutting, delivering radiation for soldering, delivering adhesives and other fluids.

FIG. 15A is a perspective and partial cross-sectional view of the compression plate apparatus shown in FIG. 3A being used in a side-to-side anastomosis while the first compression plate is held.

FIG. 15B is a cross-sectional view of the compression plate apparatus shown in FIG. 15A in the next phase as a cutter and an anvil are engaged to form an opening in the vessel.

FIG. 15C is a cross-sectional view of the compression plate apparatus shown in FIG. 15B in the next phase after the second compression plate has been compressed towards the first compression plate by an attachment actuation device such that the everted graft vessel contacts the everted blood vessel.

FIG. 16A is a perspective view of the anvil from FIG. 7C being inserted from the exterior of a blood vessel into the blood vessel lumen.

FIG. 16B is a perspective view of the blood vessel shown in FIG. 16A with the anvil depicted in phantom lines and a stay suture around the insertion opening.

1 FIG. 16C is a perspective view of the external anastomosis operator cooperating
2 with the anvil depicted in phantom lines to form an anastomosis.

3 FIG. 16D is a cross-sectional view of the compression plate apparatus shown in
4 FIG. 3A as the anvil apparatus distends a blood vessel having a stay suture around the
5 insertion opening.

6 FIG. 16E is a cross-sectional view of the compression plate apparatus shown in
7 FIG. 3A as the anvil apparatus distends a blood vessel after being inserted into the lumen
8 of the blood vessel through an insertion opening.

9 FIG. 17A is a perspective view of an externally positioned anastomosis fenestra
10 cutting apparatus inserting an anvil through an insertion opening into the lumen of a
11 blood vessel.

12 FIG. 17B is a perspective view of an externally positioned anastomosis fenestra
13 cutting apparatus distending the vessel and being readied to cooperate with an anvil.

14 FIG. 17C is a cross-sectional view and the anvil pull of the externally positioned
15 anastomosis fenestra cutting apparatus shown in FIGS. 17A-17B pulling the anvil so that
16 the engaging end of the anvil engages the cutter and forms an opening.

17 FIG. 18A is a perspective view of an externally positioned anastomosis fenestra
18 cutting apparatus cooperating with an elliptical anvil

19 FIG. 18B is a cross-sectional view and the anvil pull of the externally positioned
20 anastomosis fenestra cutting apparatus shown in FIGS. 18A pulling the anvil so that the
21 engaging end of the anvil engages the cutter and forms an elliptical opening.

22 FIG. 19A is a cross-sectional view of a spring biased externally positioned
23 anastomosis fenestra cutting apparatus after the anvil has been inserted through an
24 insertion opening.

FIG. 19B is a cross-sectional view of the spring biased externally positioned anastomosis fenestra cutting apparatus shown in FIG. 19A as the anvil pull is pulled against the cutter.

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DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

1 The present invention focuses on vascular anastomosis methods, systems, and
2 devices as well as related technology for forming the openings that are subsequently
3 anastomosed together. Numerous designs are disclosed herein for achieving the desired
4 anastomosis. The following discussion focuses mainly on the use of an intraluminally
5 directed anvil apparatus and an external anastomosis operator that work together with
6 various anastomosis plate apparatus to join vessels together. However, some features of
7 the intraluminally directed anvil apparatus can also be utilized with externally positioned
8 anvil apparatuses that are inserted into a lumen through the wall of the lumen and are
9 then utilized. Such externally positioned anvil apparatuses are also described.

10 Some of the main components that are utilized in accordance with the preferred
11 methodology for intraluminally directed anastomosis procedures include a catheter
12 system 100 and an intraluminally directed anvil apparatus 200. The catheter system 100
13 is used to remotely position the intraluminally directed anvil apparatus 200 from a
14 catheterization site to an anastomosis site. At the anastomosis site, additional main
15 components are utilized with the intraluminally directed anvil apparatus 200 including a
16 compression plate apparatus 300 and an external anastomosis operator 700. The
17 methodology for using these components is initially described in the context of joining an
18 end of an attaching vessel to a side of a receiving vessel, however, the same
19 methodology can be used with other anastomosis procedures such as side-to-side
20 anastomosis as also described below.

21 This methodology is described in the subsection below that is entitled
22 Methodology Overview. The main components are described in detail in the
23 Methodology Overview including the catheter system 100, the intraluminally directed
24 anvil apparatus 200, the compression plate apparatus 300 and the external anastomosis
25 operator 700. These components are also described and contrasted with other
26

embodiments of these components in sections entitled Anvils, Compression plate apparatus, External Anastomosis Operators. Additional methodologies for utilizing these components and alternative embodiments of these components are described in sections entitled Side-to-Side Anastomosis, Externally Directed Anastomosis, and Externally Positioned Anastomosis Fenestra Cutting Apparatus.

Methodology Overview

To optimally position intraluminally directed anvil apparatus ~~100, 200~~, catheter system 100 is utilized as shown in FIG. 1 and FIGS. 2A-2F. FIG. 1 depicts a patient undergoing the initial step of a procedure utilized to remotely position the intraluminally directed anvil apparatus 200 at an anastomosis site 10 in a blood vessel 20 (not shown in FIG. 1) in the chest or arm such as the brachial artery from a catheterization site 40 in a blood vessel in the patient's leg, the femoral artery. Catheter system 100 is shown in FIG. 1 with an introducer 110 inserted at catheterization site 40 in the femoral artery. Introducer 110 permits a guide wire 120 to be inserted to the anastomosis site. Guide wire 120 preferably utilizes a coil 125 to minimize the potential of the guide wire 120 to cause damage. Guide wire 120 typically follows a fluoroscopic device, an endoscopic device or some other remote viewing instrumentation or imaging technique used to determine the location for the anastomosis site 10 such as the proximity of a blood vessel occlusion or another abnormality that has been detected by a conventional exploration technique. Any conventional guide wire suited for inserting both diagnostic and therapeutic catheters may be utilized such as those disclosed in U.S. Pat. No. 4,846,186, which is hereby incorporated by reference in its entirety, and catheters and guide wires for vascular and interventional radiology are disclosed in *Catheters, Methods, and Injectors*, at 155-174, which is also hereby incorporated by reference in its entirety.

Hub 115 is ~~shows~~ shown at the proximal end of guide wire 120 in FIG. 1. The proximal end of a catheter system such as catheter system 100 comprises one or a

1 plurality of access ports or luer fittings such as hub 115. For the purpose of simplicity,
2 the proximal end of the various catheters depicted in FIG. 2A-2E are not shown.
3 However, the manufacture and handling of a catheter system with a plurality of lumens
4 and a plurality of access ports are known to those of ordinary skill in the art. For
5 example, U.S. Pat. Nos. 5,662,580 and 5,616,114, which have herein been incorporated
6 by reference in their entirety, disclose catheters with a plurality of access ports or luer
7 fittings and a plurality of lumens.

8 FIG. 2A is an enlarged partial cross-sectional view of vessel 20 with coil 125 of
9 guide wire 120 positioned at the selected anastomosis site 10. Once guide wire 120 has
10 been positioned at anastomosis site 10, then a positioning catheter 140 and a straightening
11 catheter 130 are pushed along guide wire 120 until they reach the anastomosis site 10.
12 Straightening catheter 130 has a tapered proximal end 135 that is adapted to minimize the
13 impact of the positioning catheter 140 as they are advanced within a blood vessel. Once
14 the straightening catheter 130 and positioning catheter 140 reach the anastomosis site 10,
15 then guide wire 120 can be removed as shown by the phantom lines in FIG. 2A. Guide
16 wire 120 is removed by pulling its distal end (not shown) that extends out of
17 catheterization site 40 until guide wire coil 125 exits the catheterization site.

18 FIG. 2B depicts the next phase of utilizing catheter system 100. Positioning
19 catheter 140 is designed to have an inherent curvature or curved memory at its distal end.
20 In order to enable positioning catheter 140 to be moved as needed while moving through
21 the patient's body to the anastomosis site, straightening catheter 130 extends within
22 positioning catheter ~~130-140~~ in order to straighten positioning catheter 140. Guide wire
23 120 also assists in providing resistance to the inclination of the distal end of the
24 positioning catheter ~~130-140~~ to curve. Once anastomosis site 10 has been reached and
25 the guide wire 120 has been removed, then catheter system 100 appears as shown in FIG.
26 2A. The straightening catheter 130 is then withdrawn as shown in FIG. 2B, to permit the

1 distal end of the positioning catheter 140 to curve against the wall of blood vessel. An
2 arrow is shown in FIG. 2B to indicate that a penetration catheter 150 containing a
3 penetration wire 160 is inserted into straightening catheter ~~140-130~~. The straightening
4 catheter can be removed at this point as indicated by the arrow in FIG. ~~2b-B~~ or it can
5 remain.

6 FIG. 2C depicts penetration catheter 150 and penetration wire 160 extending
7 through an initial piercing 15 at anastomosis site 10 through the wall of blood vessel 20.
8 Penetration wire 160 has a distal end 165 that is sharp and pointed to enable it to pierce
9 through the blood vessel wall. Once the pointed distal end 165 of penetration wire 160
10 has pierced through the blood vessel wall then penetration catheter 150 can also be
11 pushed or pulled through the blood vessel wall.

12 FIG. 2D depicts catheter system 100 once positioning catheter ~~130-140~~ and
13 straightening catheter ~~140-130~~ have been removed from around penetration catheter 150
14 and once penetration wire 160 has been removed from within penetration catheter ~~160~~
15 150. At this point, penetration catheter 150 extends from catheterization site 40 (not
16 shown in FIG. 2D) to anastomosis site 10 through the wall of blood vessel 20 at initial
17 piercing 15. Catheter system 100, more particularly, penetration catheter 150 of catheter
18 system 100 can then be used in association with the intraluminally directed anvil
19 anastomosis apparatus 200.

20 FIG. 2E shows penetration catheter 150 with its proximal end in a partial broken
21 view to indicate that the anvil pull 230 of the intraluminally directed anvil apparatus 200
22 has been inserted into penetration catheter 150 such that anvil pull 230 extends through
23 penetration catheter 150 from the proximal end of penetration catheter 150 at the
24 catheterization site 40. Intraluminally directed anvil apparatus 200, referred to in
25 abbreviated form as an anvil apparatus, includes an anvil 210 having an engaging end
26 212 from which the anvil pull 230 extends. Once the distal end 232, referred to herein as

1 a penetration end of anvil pull 230, extends beyond the distal end of penetration catheter
2 150, then penetration end 232 alone or in combination with the distal end of penetration
3 catheter 150 can be grasped so that the engaging end 212 of anvil 210 is brought into
4 contact with the interior, specifically the intima, of the vessel.

5 As shown in FIG. 2F, once the engaging end 212 of anvil 210 is brought into
6 contact with the interior 22 of the wall of vessel 20 then penetration catheter 150 is
7 removed. At this point, all components of catheter system 100 have been removed and
8 only anvil 210 of anvil apparatus 200 remains in the lumen 28 of vessel 20.

9 The length of anvil pull 230 and the length of the various elements of catheter
10 system 100 are suitably chosen depending on the distance from the catheterization site to
11 the anastomosis site. For example, this length would be approximately 180 cm long,
12 depending on the patient's height, if an anastomosis were to be performed in a blood
13 vessel in the arm such as the brachial artery, and catheter apparatus 100 were inserted
14 into the femoral artery.

15 In another embodiment of an anvil apparatus 200' described below in reference
16 to FIG. 9, the anvil apparatus may be positioned through the use of a catheter system that
17 comprises only a single catheter such as positioning catheter 140. Since anvil apparatus
18 200' is positioned at an anastomosis site by passing through a catheter such as positioning
19 catheter 140, it is necessary for the catheter to have dimensions that accommodate the
20 diameter or width of the anvil to be inserted. In some of the experiments performed in
21 the context of this invention, a catheter characterized as a 13 French sheath, also known
22 as a 4.3 mm catheter —1 French unit = 1/3 mm—, has been found suitable for most anvil
23 apparatus insertions. Catheterization techniques are described, for example, by
24 Constantin Cope and Stanley Baum, *Catheters, Methods, and Injectors for Superselective*
25 *Catheterization*, in *Abrams' Angiography*, edited by Stanley Baum, 4th ed., (this work
26 will hereinafter be referred to as "*Catheters, Methods, and Injectors*") which is hereby

1 incorporated by reference in its entirety. However, as described above, it is preferable to
2 utilize an anvil apparatus such as anvil apparatus 200 and to position the anvil against the
3 wall of the blood vessel by pulling the anvil pull 230 after it has been inserted into a
4 penetration catheter ~~160-150~~. Penetration catheter need only be a 5 French sheath to
5 receive the anvil pull 230 of most anvil apparatus.

6 FIG. 2F shows that once anvil apparatus 200 has been positioned at anastomosis
7 site 10 such that anvil pull 230 extends out of blood vessel 20 through initial piercing 15
8 in the wall of the first vessel then anvil pull 230 can be maneuvered to hold engaging end
9 212 of anvil 210 against interior 22 of the wall of blood vessel 22. Note that since initial
10 piercing 15 is so much smaller than engaging end 212 of anvil 210, anvil 210 cannot pass
11 through initial piercing 15. This difference in size enables anvil 210 to be pulled against
12 interior 22 in a manner such that the wall of vessel 20 can be distended. As discussed
13 below, the ability to pull anvil pull 230 such that engaging end 212 of anvil 210 engages
14 interior 22 and distends the wall of vessel 20 contributes significantly to the ability to
15 evert the portions of the vessel wall around an opening or anastomosis fenestra used for
16 attaching another vessel. Anvil 210 also has a cylindrical landing 214 which are its
17 sidewall surfaces that assist in the eversion process as described below in reference to
18 FIGS. 4A-4D.

19 Anvil 210 and anvil pull 230 are preferably fixedly attached together. As shown,
20 anvil pull 230 extends through anvil 210 via an anvil aperture 216 (not shown) and
21 terminates at a stopping element 236. Since the anvil pull is typically metal and the anvil
22 is typically molded plastic, stopping element 236 may be just the proximal end of anvil
23 pull 230 embedded in anvil 210 such that it is still visible. Of course, the proximal end
24 may be embedded in a way such that it is not visible as shown in FIG. 9B. In the
25 embodiment shown in FIG. 2F, the stopping element 236 is the proximal end of anvil pull
26 230 that has been bent so that it is partially embedded in terminal end 218 of anvil 210.

1 As described below, anvil 210 and anvil pull 230 may also be integral. Additionally,
2 anvil 210 may be movably positioned on anvil pull 230 in which case, stopping element
3 ~~23-236~~ can be used to brace against terminal end 218 of anvil 210.

4 After the anvil 210 has been positioned such that its engaging end 212 contacts
5 the intima of vessel 20 with anvil pull ~~210-230~~ extending through the wall of vessel 20,
6 then anvil apparatus is ready to be utilized in an anastomosis procedure for joining vessel
7 20 with another vessel such as graft vessel 50 which may be any synthetic graft vessel
8 such as ePTFE tubular grafts. Numerous approaches are disclosed herein for joining a
9 portion of a first vessel that define a first vessel opening to a portion of a second vessel
10 that defines a second vessel opening such that the first vessel and the second vessel are
11 anastomosed together and are in fluid communication. A preferred approach involves the
12 use of compression plates that provide for a desired degree of eversion of the vessels
13 without requiring penetration of the vessels. An example of such compression plates is
14 the guided compression plate apparatus shown in FIG. 3A. Guided compression plate
15 apparatus 300 is described in greater detail under the section titled Compression plate
16 apparatus.

17 As can be seen from FIG. 3B, a graft vessel 50 is loaded onto holding tabs 314b
18 of compression plate ~~314-310b~~ while a cutter 400 is positioned to be loaded into the
19 lumen 58 of graft vessel 50. Cutter 400 includes a cutting tube 410 that terminates at a
20 cutting knife 412 with a cutting edge 414. Note that a variety of cutters are disclosed
21 herein as discussed in the section entitled Cutting Devices. Once cutter 400 is positioned
22 within graft vessel 50 as shown in FIG. ~~3-4~~C, then the combination of compression plate
23 apparatus 300, graft vessel 50 and cutter 400 are ready for use with anvil apparatus 200 to
24 form an anastomosis. This combination is referred to herein as compression plate and
25 cutter assembly 390 and is used much like a cartridge in the external anastomosis
26 operator 700.

1 FIGS. 4A-4D depict the use of a compression plate apparatus 300 in combination
2 with a cutter 400 and anvil 210 in the sequential order according to the preferred
3 methodology. To optimally present this sequence, FIGS. 4A-4D are cross-sectional
4 views.

5 FIG. 4A depicts anvil 210 being pulled against the intima or interior of the vessel
6 wall such that vessel 20 is sufficiently distended to permit the vessel 20 at anastomosis
7 site 10 to be pulled into compression plate apparatus 300 through first compression plate
8 opening 320a. More particularly, anvil 210 is pulled by anvil pull 230 such that all of
9 spherical engaging end 212 is pulled into the compression plate apparatus 300 and most
10 of cylindrical landing 214. Cutter 400 also is shown in FIG. 4A extending through
11 second compression plate opening 320b about half way through compression plate
12 apparatus 300 as cutter 400 is approximated with the portion of the blood vessel 20
13 distended by anvil 210.

14 FIG. 4B depicts the formation of a first vessel opening 24 in the wall of the first
15 vessel. First vessel opening 24 is formed by pulling anvil pull 230 through cutter 400
16 sufficiently to enable anvil 210 to advance blood vessel 20 against cutting edge 414.
17 After the cut has been made then a cut portion 25 of the wall of blood vessel 20 remains
18 on spherical engaging end 212 of anvil 210 while the portion 26 of the blood vessel that
19 now define first vessel opening 24 rest on anvil landing 214. As will be discussed in the
20 Cutting Devices section and the External Anastomosis Operator section, cutter 400 is
21 preferably spring biased.

22 FIG. 4C depicts compression plate apparatus 300 after compression. More
23 particularly, compression plate 310b has been moved toward compression plate 310a by
24 sliding on guides 330 that extend from compression plate 310a. Note that the everted
25 portion 56 of graft vessel 50, more particularly the portion 57 opposite from the rounded
26 tip 316b, is urged against portion 26 that defines first blood vessel opening 24 in a

1 manner such that portion 26 has been everted. The end result is that the portion 27
2 opposite from rounded tip 316a is held in contact with the portion 57 of vessel 50
3 opposite from distal rounded tip 316b.

4 As shown in FIG. 4D, after compression plate apparatus 300 has been
5 compressed to join portion 26 of blood vessel 20 that defines first vessel opening 24 to
6 portion 56 of second vessel 50 that defines graft vessel opening 54 then first vessel 20
7 and second vessel 50 are anastomosed together and are in fluid communication. Anvil
8 apparatus 200 and cutter 400 have been removed upon the completion of the procedure
9 through lumen 58 of graft vessel 50. More particularly, once the anastomosis is
10 completed then anvil pull 230 is pulled so that it draws anvil 210 through openings 320a
11 and 320b of compression plate apparatus 300 such that anvil apparatus 200 is removed
12 along with cutter 400 through lumen 58. Note that terminal ends 332 of guides 330 have
13 been removed since they are no longer necessary. Compression plate 310b does not
14 slide on guides 330 after being compressed due to a frictional engagement. Several
15 methods for achieving this frictional engagement are described below in the Compression
16 Plate Apparatus section below. Compression plate apparatus 300 utilizes a simplistic and
17 yet effective frictional engagement as the guide apertures 334 in guide plate 310b are
18 sized such that significant force is required to move plate 310b on guides 330.

19 There are significant advantages to combining vessels in accordance with the
20 methodology described above especially in a manner such that there is at least partial
21 eversion, contact between the everted surfaces and no penetration of the portions of the
22 vessels defining the vessel openings. Of course, the anastomosis is fluid tight to normal
23 systolic pressure and remains intact under stress. Since the everted portions 26 and 56
24 respectively cover the holding tabs 314a-b, no intraluminal foreign material is exposed
25 and no subintimal connective tissue is intraluminally exposed. As a result, the
26 thrombogenicity of the anastomoses is no greater than that of hand sutured anastomosis.

1 Additionally, the configuration also results in an anastomosis that is morphologically
2 satisfactory, including complete eversion of the receiving blood vessel intima with
3 apposition to graft vessel. Further, everted portions 26 and 56' 56 are in intima-intima
4 contact and no cut portion is significantly exposed to the blood flow that is to circulate through the :

5 In addition to the results achieved, there are also significant procedural
6 advantages. The method does not require temporary occlusion of blood flow to the target
7 blood vessel. The anastomosis can be reliably created. Additionally, the anastomosis is
8 rapidly achieved and eliminates the need for high skilled suturing. For example, once the
9 anvil pull extends through the wall of the vessel, the anastomosis procedure can be
10 accomplished in as little as 60 seconds when compression plates are used to join the
11 vessels.

12 Manual manipulation may be utilized to achieve the steps shown in FIGS. 4A-
13 4D, however, mechanization is preferred. More particularly, anvil pull 230 may be
14 manually pulled as cutter 400 is held or manually advanced. Additionally, compression
15 plate apparatus may be manually compressed in some embodiments. Accordingly,
16 components are not depicted in FIGS. 4A-4D for achieving these steps. However, as
17 discussed in detail in the Compression Plate Apparatus section, Cutting Devices sections,
18 and in the External Anastomosis Operator section, these steps are preferably achieved
19 through the use of devices specifically adapted for these purposes.

20 FIGS. 5A-5B depict the use of an optional second compression plate adaptor
21 610b in combination with compression plate and cutter assembly 390 as shown in FIG.
22 3B in preparation for use with the external anastomosis operator shown in FIGS. 6A-6E
23 at 700. The purpose of optional second compression plate adaptor 610b is described
24 below in relation to the attachment actuation device 600. Note that there is a cross-
25 sectional view of compression plate and cutter assembly 390 and optional adaptor 610b
26 in FIG. 6C.

FIG. 6A provides a perspective view of external anastomosis operator 700 with its main components identified including: cutter 400, spring biasing device 450, an anvil pull engager 500 which includes an anvil pull holder 530 and an anvil pull advancer 560, and an attachment actuation device 600. Spring biasing device 450 is used to apply pressure against the distal end 418 of cutter 400. The advantages of using a spring biased cutter are explained below in the Cutting Devices section. Anvil pull 230 is fed through cutter 400, through spring biasing device 450 and into an anvil pull holder 530. An anvil pull holder 530 is preferably a clamp assembly adapted to hold anvil pull 230 extending from anvil 210 such that holder 530 is locked into position on anvil pull 230. Anvil pull advancer 560 is adapted to pull anvil pull 230 once anvil pull 230 is held by holder 530. As anvil pull advancer 560 pulls on anvil pull 230, it causes anvil pull 230 to advance within compression plate assembly 300 and distend the wall of vessel 20 until cutter 400 is engaged. Anvil pull holder 530 and anvil pull advancer 560 are described in greater detail below in the External Anastomosis Operator section in reference to FIGS. 6A-6E.

As shown in FIG. 6C, the assembly depicted in FIG. 5B is inserted such that the first compression plate 310a is held via adaptor 610a and the second compression plate 310b is held via adaptor 610b while distal end 418 of cutter 400 abuts spring biasing device 450. Anvil pull 230 is shown in FIG. 6C extending through cutter 400. Cutter 400 is hollow so it has a chamber 420 between the sidewalls of cutting tube 410. Cutter 400 may also have an optional centering core 422 that extends at least part way through chamber 420. Centering core 422 has a centering conduit 424 that assists in centering anvil pull 230 in cutter 400 such that anvil pull 230 is essentially parallel with the sidewalls of cutting tube. As discussed below in greater detail, it is not always necessary for cutter 400 to have a centering core or for other cutters to have a centering core or a centering conduit. When the engaging end of the anvil is spherical and the cutter is spherical and is configured such that it permits part of the spherical engaging end of the

1 anvil to be positioned in cutter chamber then the cutter self centers on the spherical
2 engaging end.

3 As shown in FIG. 6D, anvil pull 230 is inserted through cutter 400, through
4 spring biasing device 450 and into an anvil pull holder 530. Holder knob 540 of anvil
5 pull holder 530 is then rotated as described below to hold anvil pull 230. Once anvil pull
6 holder ~~230-530~~ securely holds anvil pull, then advancer knob 570 is rotated as shown in
7 FIG. 6D. Rotation of advancer knob 570 causes anvil pull holder 530 to pull on anvil
8 pull 230, which causes anvil pull 230 to advance within compression plate assembly 300
9 and distend the wall of vessel 20 until cutter 400 is engaged as depicted. Note that FIG.
10 4B depicts anvil 210 engaging cutter 400 at the same point in the process as is shown in
11 FIG. 6D except FIG. 4B does not show any of the components of external anastomosis
12 operator being used.

13 FIG. 6E depicts attachment actuation device 600 being engaged. As explained
14 above in reference to FIGS. 4A-4D, once the anastomosis fenestra or vessel opening 24
15 has been made then compression plate assembly 300 can be compressed such that first
16 and second compression plates 310a-b are brought together. As indicated above,
17 compression plates 310a-b are preferably approximated through the use of appropriate
18 devices. Attachment actuation device 600 achieves this purpose. Attachment actuation
19 device 600 is also described in detail below in the External Anastomosis Operator section
20 in reference to FIGS. 6A-6E. However, to appreciate the advantages of the preferred
21 methodology it should be understood that attachment actuation device 600 is used to
22 bring the compression plates together in the manner depicted in FIGS. 4A-4D.
23 Attachment actuation device 600 has a first plate engager 600a and a second plate
24 engager 600b. These plate holders 600a-b may directly hold first and second
25 compression plates 310a-b or optional adapters 610a-b may be utilized. FIGS. 12C-12F
26 depict another embodiment of an attachment actuation device 600' configured to hold

1 compression plates without adapters. Note that compression plate apparatus 300'
2 depicted in FIGS. 12C-12F is another embodiment of a compression plate apparatus with
3 plates that snap-fit together. First plate engager 600a is fixedly mounted on a rail 640
4 while second plate engager 600b is movably mounted on rail 640. Second plate engager
5 600b is preferably glidably mounted on rail 640 with a fixed orientation such that it can
6 be advanced toward first plate engager 600a to compress the compression plate apparatus
7 300. Second plate engager 600b is held in a fixed orientation due to the position of
8 groove pin 644 extending through or from rail 640 which is positioned in groove 634 of
9 first plate engager 600a. Note that as shown below in reference to FIG. 15A-15C, the
10 attachment actuation device need not be part of the same apparatus with the anvil pull
11 engager and the cutter.

12 **Anvils**

13 As discussed above in reference to anvil 210, the anvil provides a surface at its
14 engaging end for engaging the cutter. The engaging end is also in direct contact with the
15 blood vessel's intima at the anastomosis site when the anvil abuts the receiving blood
16 vessel wall. The term "anvil" is meant to encompass objects with the characteristics
17 described herein which present at least one surface that is adapted to engage a cutter.

18 The anvil is preferably sized at its engaging end to have a greater cross-sectional
19 area than a cross-sectional area defined by the perimeter of the cutting edge of the cutting
20 device such that portions of the engaging end of the anvil extend beyond the cutting edge
21 when the cutting device engages the anvil and forms the first vessel opening. This size
22 differential is particularly useful for cutting when the cutting device is a mechanical
23 cutter or knife as it permits the anastomosis fenestra or vessel opening to be formed
24 through the action of the cutting edge 414 ~~be~~being pressed against engaging end 212.
25 This is a significant improvement over conventional cutting techniques that involve the
26

1 external positioning of an anvil into the lumen of a vessel that is smaller than the cutter so
2 that the vessel is cut as the cutter passes over the anvil. Such conventional cutting
3 techniques operate much like a typical hand held paper punch used for forming holes by
4 pushing a cutter over an anvil. Just like paper punches such vascular punches often fail
5 to fully make the cut and leave a portion attached. The connective tissue in blood vessels
6 in combination with the moist condition of the blood vessels further limit the
7 effectiveness of such prior art cutting techniques. More particularly, cutting a moist
8 highly interconnected material by squeezing it between the anvil and the cutter often
9 results in part of the tissue merely slipping between the anvil and the cutter such that a
10 portion is still attached.

11 In addition to cutters that are essentially tubular knives, additional cutting
12 devices are described below in the section entitled Cutting Devices. These cutting
13 devices include devices that utilize a radiation source, such as a surgical laser, that emit
14 radiation of the appropriate characteristics to open the anastomosis fenestra in the
15 receiving blood vessel wall. Such cutting devices that utilize radiation to ablate the
16 vessel wall are also preferably used with an anvil having a cross-sectional area at its
17 engaging end that is larger than the cross-sectional area defined by the perimeter of the
18 cutting edge of the cutting device. While it is useful to have an anvil with an engaging
19 end that extends beyond the cutting edge or the perimeter of the portion that cuts through
20 the use of radiation to localize the impact of the cut, such as minimization of heat
21 transfer, the engaging end need not necessarily be larger for use with such cutting
22 devices.

23 Anvil 40 is preferably made of a puncture resistant material that can withstand
24 the abrasive action of a cutting element. For example, anvil 210 may be formed from a
25 hard plastic material such as Delrin ® acetal resins or a high density polyurethane or from
26 a metal such as stainless steel in order to withstand the abrasive action of a cutting

1 device or of a sharp pointed end. When cutting the anastomosis fenestra with radiant
2 energy, the anvil of this invention is preferably coated with radiation absorbing material
3 that prevents radiation scattering. Such coated anvil embodiments are hereinafter
4 referred to as "laser shielded anvils".

5 FIGS. 7A-7D provides examples for several embodiments of the anvil of this
6 invention. A line 248 is a visual aid drawn through anvils 210a-d to clearly indicate that
7 the portion of the anvil extending from line 248 to the anvil pull is the engaging end
8 212a-d. Engaging ends ~~210~~212a-c are all spherical engaging ends like spherical
9 engaging end 212 of anvil 210. Note that these spherical engaging ends are essentially a
10 hemisphere at the side of the anvil proximal to the anvil pull 230. When the cutting
11 device is cylindrical and is configured such that it permits part of the spherical engaging
12 end of the anvil to be positioned in the chamber 420 then the cutter self centers on a
13 spherical engaging end.

14 Landing 214 of anvil 210 is also useful feature when the anvil is used in
15 combination with a compression plate apparatus or some of the means for joining a
16 portion of the first vessel that defines the first vessel opening to a portion of a second
17 vessel that defines a second vessel opening such that the first vessel and the second vessel
18 are anastomosed together and are in fluid communication. As noted above, landing 214
19 is essentially the surface of the cylindrical portion of anvil 210. When an anvil with a
20 spherical engaging end and cylindrical landings such as anvil 210 is used with a
21 compression plate apparatus such as apparatus 300 then the spherical engaging end can
22 extend through first compression plate opening 320a and into the apparatus while landing
23 214 abuts the wall of blood vessel 20 against holding tabs 314a. The tolerance between
24 landing 214 and holding tabs 314a is such that landing 214 initially rests against holding
25 tabs 314a until sufficient force is applied to pull anvil 210 through compression plate
26 apparatus 300. As shown in FIGS. 4B-4C and FIGS. 12D-12E, landing 214 assists in the

1 eversion process before anvil 210 is pulled through the compression plate apparatus.
2 More particularly, landing 214 enables the portion 26 defining the first vessel opening 24
3 to be everted as everted portion 56 of graft vessel 50 is pushed against portion 26. As
4 everted portion 56 pushes against portion 26, portion 26 curls up and over holding tabs
5 314a. This process preferably fully everts portion 26, however, satisfactory results are
6 obtained even if portion 26 is only partially everted.

7 FIG. 7A depicts an anvil 210a that has a landing 214a which is slightly flared so
8 that it tapers toward the engaging end 212a. This may further assist in achieving a
9 desired eversion. FIG. 7B shows an anvil 210b having a rounded flange at its terminal
10 end 218 which may also assist in everting the portion of the vessel that defines the vessel
11 opening.

12 FIG. 7C depicts an anvil 210c that has a spherical engaging end ~~48-212c~~ opposite
13 from a tapered terminal end. As explained below, many features described herein in
14 reference to an intraluminally positioned anvil apparatus also relate to an externally
15 directed anvil apparatus. As shown in FIGS. 16A-16E, FIGS. 17A-17C, FIGS. 18A-18B,
16 FIGS. 19A-19B, an anvil 210 may be inserted through a wall of a blood vessel at an
17 insertion opening that has been selected as an anastomosis site and positioned in a lumen
18 of the first vessel with the anvil pull 230 extending through the insertion opening of the
19 blood vessel. Note that such use may require some modifications. For example, use of
20 an anvil with a tapered end such as tapered end 218c minimizes the size needed for the
21 insertion opening since the vessel wall can stretch as the taper of the anvil increases.

22 FIG. 7D depicts an anvil 210d having an elliptical engaging ends that is adapted
23 to receive a cutter with a corresponding elliptical configuration for the formation of
24 elliptical openings in vessels. As described in greater detail in reference to FIGS. 14A-
25 14C and FIGS. 16A-16B, it is often necessary to attach vessels in a nonperpendicular
26 configuration such that it is Y-shaped instead of T-shaped. Like anvil 210c, anvil 210d

1 has a tapered terminal end for ease in use as an externally positioned anvil apparatus.
2 While reference is made to spherical engaging ends it should be noted that noncircular
3 engaging ends that are convex such as the elliptical engaging end of anvil 210d may also
4 be utilized to achieve the desired eversion, particularly when the anvil has an
appropriately configured landing.

5 FIG. 8 depicts another embodiment of an anvil apparatus 200'. Anvil apparatus
6 200' has a positioning stem 240' used to push anvil 210 to the anastomosis site through a
7 positioning catheter 140'. Accordingly, when using anvil apparatus 200' it is not
8 necessary to utilize a piercing catheter or a piercing wire. Note also that anvil apparatus
9 200 has an anvil pull with a sharp piercing end 232' instead of a blunt or rounded
10 penetration end 232 like anvil apparatus 200. The pointed configuration of piercing end
11 232' enables it to make initial piercing 15 in the wall of vessel 20 by puncturing the wall
12 from its intima outward without causing undue tearing around the puncture. Piercing end
13 232' is then pulled from the outside of receiving blood vessel 20 just like penetration end
14 232 of anvil pull 230. Note that anvil pull 230 of anvil apparatus 200 may have either a
15 distal end that is rounded or blunt like penetration end 232 or sharp such as piercing end
16 232'.

17 Anvil apparatus 200' is not shown with a stopping element such as stopping
18 element 236 of anvil apparatus 200. Anvil apparatus 1000 in FIG. 17A also is not shown
19 with a stopping element as its anvil pull and anvil are integral. However, anvil apparatus
20 200 may utilize a stopping element such as the stopping elements discussed in detail in
21 the above section entitled Methodology Overview. For embodiments with an anvil that is
22 nonintegral with the anvil pull, the stopping element holds anvil stationary relative to the
23 anvil pull such while withstanding a pressure exerted at the engaging end of the anvil due
24 to the resistance exerted by the receiving blood vessel wall being distended by the anvil
25 and the pressure of the cutting device against the engaging end.
26

1 Anvil apparatus 200' is positioned through positioning catheter 140' by first
2 introducing anvil pull 230' and then pushing positioning stem. When the anastomosis
3 site is reached, then anvil pull 230' is pushed out of positioning catheter 140' and through
4 initial piercing 15 until the engaging end 212' of anvil 210' abuts the interior of the wall
5 of vessel 20. Catheter 140' may be positioned within lumen 28 of blood vessel in the
6 same manner as catheter 140.

7 Distal end 142' may be adapted for providing a lateral exit for piercing end 232'
8 of anvil pull ~~230~~230'. Distal end 142' may have a deflecting surface and a lateral
9 aperture that guides piercing end 232' towards the intima of receiving blood vessel 20.
10 Because piercing end 232' is very sharp, such deflecting surface is preferably a puncture
11 and abrasion resistant surface. In addition, distal end 142' may have an appropriate
12 marker for imaging the orientation of the aperture at distal end 142 and/or the position of
13 distal end 142 itself. Such radio-opaque markers can be any of the radio-opaque markers
14 known in the practice of angiography. Similarly, all of the catheters used in the
15 anastomosis procedure may have radio-opaque portions. Anvil pull 230' is typically
16 radio-opaque itself, although very thin embodiments of this wire are preferably coated
17 with a material such as gold or a bio-compatible barium-containing substance to make
18 them more visible. Catheter distal end configurations for directing outwardly an
19 elongated member have been disclosed in U.S. Pat. Nos. 4,578,061, 4,861,336,
20 5,167,645, 5,342,394, and 5,800,450, which are hereby incorporated by reference in their
21 entirety.

22 The dimensions of any of the embodiments of the anvil of this invention are
23 determined by the size of the lumen of the receiving vessel and by the dimension of the
24 passage that will ensure the fluid communication between the graft vessel and the
25 receiving vessel after they have been anastomosed. These dimensions are typically
26 chosen or known in the art. For example, when a graft vessel of about 4 mm in diameter

1 is to be anastomosed to a receiving blood vessel which has an approximate lumen
2 diameter of about 8 mm, the diameter of anvil at its widest may range from about 3 mm
3 to about 6 mm. So for anvil 210, the diameter at landing 214 may range from about 3
4 mm to about 6 mm for use in such a vessel. However, the anvil may have any suitable
5 size that enables it to be positioned as needed. Note that the anvil is preferably designed
6 so that the blood flow through the receiving blood vessel will preferably not be
7 interrupted during the anastomosis. However, the design can be such that the blood flow
8 is interrupted when this feature is desired.

9 FIGS. 9A-9B, FIGS. 10A-B and FIGS. 11A-B each depict an anvil apparatus
10 with an anvil that is deployable after reaching the anastomosis site such that they have an
11 expanded size when needed. FIGS. 9A-9B and FIGS. 10A-B depict mechanically
12 deployable anvils while FIGS. 10A-10B depict a chemically deployable anvil.

13 The anvil apparatus depicted in FIGS. 9A-9B is identical to that of anvil
14 apparatus 200 except anvil 210 is smaller and two flexible anvil sheaths 260a-b are
15 positioned on anvil pull 230. Flexible anvil sheaths 260a-b are adapted to be nested as
16 shown in FIG. 9B once the wall of vessel 20 is encountered to cause the flexible anvil
17 sheaths 260a-b to be dislodged from their positions on anvil pull 230. Anvil sheaths
18 260a-b may be retained in their spaced positions on anvil pull through reliance on a tight
19 frictional fit or stops may be utilized to ensure that the sheaths are not dislodged until
20 desired at the anastomosis site through application of an appropriate amount of force.
21 When nested on anvil 210, flexible sheaths 260a-b and anvil 230 act together as an anvil.
22 The anvil sheaths may be relatively soft compared to anvil 230 so it may be necessary to
23 treated the anvil sheaths with a puncture resistant material or an abrasion resistant
24 material.

25 FIGS. 10A-10B depict a flexible anvil 210'' that is narrow when collapsed and
26 becomes wider when its engaging end 212'' encounters the wall of blood vessel 20. The

engaging end 212'' of anvil 210'' is not attached to anvil pull 230, only terminal end 218'' is attached to anvil pull. Since anvil 210'' is hollow, it can flex into an expanded or deployed position when engaging end 212'' is pushed toward terminal end 218''.

FIG. 11A depicts a balloon anvil 210''' in a deflated condition extending from a hollow tubular anvil pull 230''. FIG. 11B depicts balloon anvil 210''' deployed in an inflated condition ready for engagement against the interior of a vessel at an anastomosis site. Balloon anvil is preferably chemically deployed by being filled with a polymerizable material that hardens in situ. For example, syringe 280 may be coupled to tubular anvil pull 230 to enable a composition to be delivered that includes conventional monomers that rapidly polymerizes in the presence of appropriate chemical initiators.

For example, the monomers may be suitable acrylates such as urethane dimethacrylate, p-hydroxyphenyl methacrylamide, butane diol dimethacrylate, and bisphenol-A-diglycidyl dimethacrylate ("Bis-GMA"). Examples of appropriate chemical initiators include a wide range of peroxides, other per components, and other free radical generators. An appropriate two-part chemical curing system typically includes a peroxide constituent in one part and an amino compound in another. Exemplary peroxides include benzoyl peroxide, 2-butanone peroxide, lauroyl peroxide and tert-butyl peroxide. Examples of amino compounds include dimethylamino ethyl methacrylate, triethyl amine, 2-dimethylamino ethanol, diethylamino ethyl methacrylate, trihexyl amine, N,N-dimethyl-p-toluidine, N-methylethanolamine, and 2,2'(p-tolyimino) diethanol.

After the polymerizable material, the mixture of monomers and chemical initiators, has been delivered into balloon anvil 210''' then it is necessary to wait for the material to polymerize such that anvil 210''' is hard. As shown in FIG. 11B, once the polymerizable material has hardened then anvil pull 230'' is anchored in polymerized material 222 and polymerized material 222 is surrounded by balloon 220. Since anvil

1 pull 230'' is anchored in polymerizable material 222, balloon anvil 210 can be used in a
2 cutting process without regard to the softness of balloon 220. More particularly, if a
3 cutter 400 presses through balloon 220 then it merely rests on the exposed polymerized
4 material 222 with the cut portion of blood vessel 20 and is removed along with the entire
5 anvil apparatus 200''.

6 Balloon anvil may also be merely inflated with gas or an appropriate fluid;
7 however, such a balloon anvil is best utilized with embodiments that do not require the
8 anvil to be puncture resistant such as a cutting device that uses radiation followed by
9 steps such as gluing, welding or soldering to join the vessels together. Of course, it may
10 be necessary to treat the engaging end of a balloon anvil such that it is laser shielded by
11 placing a laser shield material at the engaging end of the balloon anvil. One example of a
12 laser shield material is a shield consisting of a sandwich of polymethylmethacrylate and
13 tinfoil that is known to provide corneal and retinal protection from inadvertent injury
14 during argon, Nd-YAG or dye laser treatment at the tested laser power outputs.
15 Similarly, the balloon anvil may be treated with an appropriate material such that it is
16 puncture resistant or distortion resistant.

17 The balloon may also be a puncture resistant balloon. Puncture and scratch
18 resistant balloons have been disclosed in U.S. Pat. Nos. 5,766,158, 5,662,580, 5,620,649,
19 5,616,114, 5,613,979, 5,478,320, 5,290,306, and 5,779,731, which are hereby
20 incorporated by reference in their entirety. In still another embodiment of this invention,
21 the anvil of this invention can be embodied by the combination of a balloon and a
22 puncture resistant balloon sheath. A balloon plus balloon sheath combination has been
23 disclosed in U.S. Pat. No. 5,843,027 which is hereby incorporated by reference in its
24 entirety.

25 In summary, the anvils are configured in a way such that it effectively cooperates
26 with the cutting device to form the opening of the anastomosis fenestra. The anvils also

1 cooperates in the eversion of the edge of the anastomosed fenestra. Furthermore, the
2 anvil of the present invention is configured so that it can abut the receiving blood vessel
3 wall at the anastomosis site from the intraluminal space of such blood vessel. In addition,
4 the anvil of this invention is configured so that it effectively cooperates with the
5 compression plate apparatus in the joining of the anastomosed structures. The anvils
6 disclosed herein are all examples of anvil means for engaging the interior surface of a
7 first vessel at an anastomosis site. The anvil means that are part of an intraluminally
8 directed anvil apparatus are more specifically anvil means for engaging the interior
9 surface of the wall of a first vessel at an anastomosis site wherein the anvil means is sized
10 to pass within the lumen of the first vessel from an insertion site to a remotely located
11 anastomosis site.

12 **Compression Plate Apparatus**

13 As indicated above, the plates are configured so that they provide support to the
14 everted openings of the anastomosed structures and facilitate the eversion of the receiving
15 blood vessel, the vessel to which another vessel is being attached that has been everted
16 before initiating the procedure. The compression plate apparatus also eliminate the need
17 for skilled suturing. Use of the compression plate apparatus makes anastomosis
18 procedures more efficient in a reliable manner. Additionally, the compression plate
19 apparatus holds the anastomosed structures in an effective leak proof contact
20 engagement.

21 In each compression plate, the side which is in contact with the everted contour
22 of the anastomosed structure is described as the anastomosis side. In the practice of an
23 anastomosis according to this invention, compression plates are used in a way such that
24 the anastomosis sides of the two compression plates are opposite to each other. Preferred
25 embodiments of compression plates have a generally annular shape with interior
26

1 openings which have a generally circumferential contour; the internal diameter of each
2 one of these openings is such that the corresponding portion of the vessel to be
3 anastomosed can fit therein. Typically, this internal diameter is approximately equal to,
4 or slightly greater than, the external diameters of the corresponding portion of the vessel
5 to be anastomosed. An internal diameter slightly greater than the external diameter of
6 the corresponding portion of the vessel to be anastomosed is preferred. With this internal
7 diameter, the compression plate does not pose a significant obstacle to the periodic
8 dilation that the vessel is subject to as a consequence of the characteristics of the fluid
9 flow that circulates through the anastomosed structures.

10 There are two primary embodiments disclosed herein including the guided
11 compression plate apparatus 300 shown in FIGS. 3A-3B, FIGS. 4A-4E, FIGS. 5A-5B,
12 FIGS. 6C-6E and the snap-fit compression plate apparatus 300' shown in FIGS. 12A-
13 12G. A variation of compression plate apparatus 300 is also shown at 300'' in FIG. 13 to
14 show that a compression plate apparatus can also be used for joining vessel together in a
15 nonperpendicular orientation. Each plate has an opening 320a-b that is generally round,
16 however, as shown in FIG. 13, the openings may also be ellipsoidal, ovoid, or have other
17 noncircular configurations. The compression plate apparatus can be used in combination
18 with either an intraluminally directed anvil apparatus or an externally positioned anvil
19 apparatus.

20 Compression plate apparatus 300 is best viewed in FIGS. 3A-3B. Compression
21 plate apparatus 300 has a compression plate 310a is referred to as a first compression
22 plate or a receiving vessel compression plate while compression plate 310b is referred to
23 as a second compression plate or an attaching vessel compression plate. As discussed
24 above, compression plate apparatus 300 is shown in FIG. 3A before graft vessel 50 has
25 been loaded onto holding tabs 314b of second compression plate 310b while FIG. 3B
26 shows graft vessel 50.

1 Compression plates 310a-b are provided in the exemplary embodiment shown in
2 FIG. 3A with a plurality of holding tabs 314a-b respectively protruding from opposing
3 anastomosis sides 322a (~~not shown~~) and 322b of compression plates 310a-b. More
4 particularly, holding tabs 314a-b extend respectively from rings 312a-b of compression
5 plates 310a-b. Holding tabs 314a-b are intended to hold the everted contours of the
6 structures being anastomosed. Each one of holding tabs 314a-b has a base that integrally
7 extends from the anastomosis side of the ring 312a-b of the corresponding plate at 313a-b
8 and that terminate at rounded tips ~~316~~-315a-b. Distal tips ~~316~~-315a-b are preferably
9 rounded as shown to minimize the potential for penetration. However, in some
10 embodiments, the distal tips may be pointed, for example, when holding a graft vessel.
11 Holding tabs 314a-b are typically rather rigid, however, they may also be designed to
12 elastically bend in such a way that the distal tips of such holding tabs slightly swing about
13 their respective bases. Such a bending action may be caused by the displacement through
14 any of openings 320a-b defined by holding tabs 314a-b, more particularly the distal tips
15 ~~316~~-315a-b of holding tabs 314a-b.

16 The number of holding tabs and their spacing may be varied as ~~need~~-needed as
17 long as the portions of the vessels defining the vessel openings can be maintained in an
18 everted orientation. For example, the plurality of holding tabs may include sixteen
19 holding tabs as shown in FIG. 3A. However, smaller amounts may also be utilized, for
20 example there may be only six to ten holding tabs.

21 Holding tabs such as holding tabs 314a-b can have a plurality of shapes. The
22 holding tabs preferably used in embodiments of this invention are wider at the base and
23 so configured as to extend into a distal rounded tip at the end opposite to the base.
24 Although holding tabs 314a-b can be distributed in a variety of arrays, a generally regular
25 distribution on the anastomosis sides of the compression plates is preferred.
26

Each of the holding tabs shown in the embodiment ~~schematically depicted in~~
FIG. ~~1-3A~~ is attached at its base 316a-b at the inner peripheries 313a-b of rings 312a-b.
However, the bases 316a-b may also extend from other locations of the rings. For
example, the bases 316a-b may extend from rings 312a-b between the outer peripheries
311a-b and the inner peripheries 313a-b or perimeter on the anastomosis sides 322a-b of
each annular compression plate.

Although, it is not necessary for the holding tabs in each compression plate to be
oriented relative to the holding tabs in the other compression plate in a mating
configuration, it is preferred. When referring to the relative configuration of the holding
tabs in opposing compression plates, the terms "mating or mated configuration" describe
a configuration in which each one of the holding tabs in a compression plate can
generally fit in the space between two neighboring holding tabs in the opposing
compression plate when such compression plates are close enough. As shown by the
phantom lines in FIG. 3A, holding tabs 314b are offset from holding tabs 314a such that
as the plates are brought towards each other each holding tab 314b is positioned opposite
from the spaces between holding tabs 314a in a mated configuration. When the
compression plates are brought together just close enough for the tips ~~316~~315a-b to be in
the same plane, then the everted tissue is held in place and the anastomosis is secure.
Failure to bring the compression plates sufficiently close together such that the tips ~~316~~
315a-b are significantly close together risks the potential loss of the tissue that has been
captured and everted onto holding tabs 314a-b. Note that each holding tab 314b is shown
just barely entering into an opposing space between adjacent holding tabs 314a. Of
course, the compression plates may be designed for further compression such that
holding tabs 314b further enter the space between adjacent holding tabs 314a. However,
the compression plates are preferably designed such that the plates are brought together
without penetrating blood vessel 20 or graft vessel 50. Note that guides 330 maintain the

1 orientation of the compression plates so that the respective teeth have the preferred
2 mating configuration.

3 An example of a suitable compression is provided by a compression plate
4 apparatus having holding tabs with lengths of .045 inches (.1143 cm) that has a distance
5 between the anastomosis sides 322a-b of rings 312a-b of .090 inches (.2286 cm).
6 Compression down to only .10 inches (.254 cm) for such a compression plate apparatus is
7 generally insufficient to hold the anastomosed tissues. The plates may be further
8 compressed such that the distance between the anastomosis sides 322a-b is .080 inches
9 (.2032 cm) or .070 inches (.1778 cm) to bring vessel 20 and vessel 50 even closer
10 together. However, as noted above, it is preferable to avoid pushing through the vessels.
11 The compression plate are accordingly designed to permit compression down to the ideal
12 spacing between the anastomosis sides while providing holding tabs that are long enough
13 to capture the tissue in an everted configuration.

14 The holding tabs such as holding tabs 314a-b are preferably configured in a way
15 such that they are not exposed to blood flowing through the anastomosed structures.
16 Some embodiments of this invention are provided with holding tabs that are coated with a
17 biocompatible non-thrombogenic material to prevent the formation of thrombi if such
18 holding tabs or any portion thereof becomes exposed to blood flow. An example of such
19 material is teflon.

20 Holding tabs of a variety of shapes which are distributed in varying numbers and
21 arrays on the anastomosis sides of compression plates 310a-b and equivalents thereof are
22 exemplary embodiments of means for holding a portion of a vessel that defines the vessel
23 opening. As indicated above, the holding tabs preferably hold the portion of the vessel
24 that defines the vessel opening in a manner such that the portion defining the first vessel
25 opening is at least partially everted and is not penetrated. The holding tabs disclosed
26 herein are all examples of holding means for holding a portion of a first vessel that

1 defines a vessel opening in manner such that the portion defining the vessel opening is at
2 least partially everted and is preferably not penetrated.

3 As indicated above, guides 330 permit the relative approach of these two plates
4 as compression plate 310b slides along guides 330 towards compression plate 310a.
5 More particularly, guides 330 enable compression plates 310a-b to be brought together in
6 a manner such that second compression plate 310b is moved in a fixed parallel
7 orientation relative to first compression plate 310a. Additionally, guides 330 are
8 positioned relative to holding tabs 314a-b and have a length that permits graft vessel 50
9 to be loaded onto holding tabs 314b and then be brought into contact with blood vessel
10 20. Stated otherwise, the configuration of guides 330 enables first vessel opening 24 and
11 second vessel opening 54 to be initially spaced apart and opposite from each other and
12 then to be advanced toward each other as second compression plate 310b is moved with
13 graft vessel 50 held on the holding tabs 314b while blood vessel 20 is held by holding
14 tabs 314a of compression plate 310a. As best shown in FIGS. 4A-4D, movement of
15 second compression plate 310b toward first compression plate 310a brings the portion 56
16 of graft vessel 50 that defines the second vessel opening 54 into contact with the portion
17 26 of blood vessel 20 that defines the first vessel opening 24 such that the blood vessel
18 and the graft vessel are anastomosed together.

19 Compression plate 310b is slidably mounted on guides 330 at guide apertures
20 334. To slide compression plate 310b along guides 330, each one of ends 332 of guides
21 330 is introduced through one of guide apertures 334 of compression plate 310b. Ends of
22 guides 330 opposite to ends 332 are attached to ring 312a of compression plate 310a,
23 however, guides 330 may also integrally extend from ring 312a.

24 As shown, the compression plate apparatus preferably has a plurality of guides.
25 While compression plate anastomosis 300 is shown with four guides 330, other
26 embodiments may have other configurations such that the plurality of guides includes, for

1 example, three to six guides. Further, other embodiments may have less than three or
2 more than six guides. It is even possible to have only one guide. Although guides 330
3 can be distributed in a variety of arrays, a generally regular distribution is preferred in
4 embodiments with more than one guide.

5 When compression plates 310a-b are in close proximity to each other at an
6 anastomosis site providing support to the anastomosed structures, terminal ends 332 of
7 guides 330 can extend away from compression plates 310a-b to an extent such that the
8 protrusion results in the presence of an undesirable feature in the immediate
9 neighborhood of the anastomosis site. To solve this problem, embodiments of the
10 compression plate devices of this invention are provided with guides 330 which can be
11 appropriately shortened by removing an appropriate length of terminal ends 332. In some
12 embodiments, terminal ends 332 are manufactured with a material which dissolves after
13 an appropriate time following the anastomosis. In other embodiments, guides 330 are
14 made of a material that can easily be clipped to a desired length, thus eliminating terminal
15 ends 332 as shown in FIG. 4D. In other embodiments, guides 330 can be provided with
16 notches or some other localized weakened structural feature which facilitates the easy
17 removal of terminal ends 332 at desired distances with respect to plate 310a. Still other
18 embodiments can be provided with terminal ends 332 that can easily bend to an extent
19 such that undesirable protrusions are eliminated.

20 The guides may have a variety of lengths and be distributed in varying numbers
21 and arrays. The guides may also extend from one or both of the compression plates at
22 any appropriate location. However, the guides are preferably situated such that the
23 portion 26 defining the blood vessel opening 24 and the portion 56 defining the graft
24 vessel opening 54 are joined without being penetrated as the first vessel and the second
25 vessel are anastomosed together. The guides disclosed herein are exemplary
26 embodiments of means for guiding the movement of one compression plate with respect

1 to the other compression plate. More particularly, the guides disclosed herein are
2 examples of means for guiding the movement of one compression plate relative to the
3 other such that one compression plate moves in a fixed parallel orientation relative to the
4 other compression plate.

5 Guide apertures 334 are sized to frictionally engage guides 330 in a manner such
6 that compression plate 310b does not inadvertently slide on guides 330, particularly not
7 after being compressed towards compression plate 310a. In the absence of a suitable
8 frictional engagement, compression plate 310b may slide away from compression plate
9 310a to potentially jeopardize the leak-proof character of structures held together by the
10 compression plates. An undesired separation could be caused, for example, by an
11 expansion of the anastomosed structures at the anastomosis site, caused in turn by the
12 pressure exerted by the fluid circulating therethrough.

13 When second compression plate is formed from plastic, the desired frictional
14 engagement is generally achieved whether guides 330 are made from metal or plastic.
15 However, when second compression plate is formed from metal and the guides are also
16 metal, it is preferable to utilize an alternative frictional engagement. For example, FIG.
17 5A shows compression plate apparatus 300 with an optional holding ring 340 that has a
18 friction coupling with guides 330 through its guide orifices 346. Holding ring 340 is
19 provided with opening 348 whose internal diameter is preferably at least equal to that of
20 the opening ~~220~~ 320b of compression plate 310b. The frictional engagement of holding
21 ring 340 with guides 330, like the frictional engagement described above for guide
22 apertures 334 with guides 330, is such that expansion of the anastomosed structures
23 ~~cannot~~ cannot separate compression plates 310a-b with respect to each other when
24 holding ring 340 is in contact engagement with exterior side 324b (~~not-shown~~) of
25 compression plate 310b opposite to its anastomosis side 322b. The holding ring may, for
26 example, be formed from nylon.

1 Other embodiments of this invention are provided with different frictional
2 engagements that are designed to prevent compression plate 310b from significantly
3 moving away from compression plate 310a. For example, guides 330'' of compression
4 plate apparatus 300'' in FIG. 13 have barbs 336. These frictional engagement
5 configurations described above enable the compression plates to be approached to a
6 desired relative separation and maintained at that separation. This feature also permits
7 the control of the pressure applied to the everted tissue of the anastomosed structures and
8 the compression of the plates in stages so that they are approximated in a controlled
9 manner.

10 These frictional engagements are all examples of means for locking the
11 compression plates together. More particularly, guides that engage appropriately sized
12 apertures 334 of second compression plate 330 310b for frictional engagement, a holding
13 ring 340 that has guide orifices 346 sized to fractionally engage a guide 330, and guide
14 barbs 336 for irreversible advancement of second compression plate 310b as the guide
15 extends through guide apertures 334 of second compression plate 310b are all examples
16 of means for locking the compression plates together. Note that when the frictional
17 engagement is achieved through reliance on guides that extend from a first compression
18 plate and that pass through appropriately sized apertures in the second compression plate
19 then it can be said that the first compression plate and the second compression plate have
20 means for locking the compression plates together. An advantage of such locking means
21 that are part of the first and second compression plates is that it is not necessary to
22 separately attach the locking means to the compression plate apparatus after it has been
23 used to anastomose the vessels.

24 The compression plate apparatus is preferably used for vascular anastomosis,
25 however, the present invention is not limited to such use. Nor is the compression plate
26 apparatus limited to use with any particularly sized vessel. For example, vessels may be

1 joined with diameters ranging from about 2 mm to about 20 mm, but there is no
2 fundamental limitation for using embodiments of this invention with graft vessels with
3 diameters less than 2 mm.

4 A variety of techniques known in the art can be used to manufacture
5 compression plates within the scope of this invention depending on the material used.
6 Compression plate apparatus 300, 300' and 300'' can be formed from a plastic material
7 such as nylon or from metals such as titanium or nickel/titanium alloys. Stainless steel
8 can be used but is not preferred. Additionally, one plate may be formed from a metal
9 while the other is formed from plastic. In addition to molding the plates, when the plates
10 are formed from metal, the plate may be cut from a disk in a flat configuration and then
11 the holding tabs can be bent into position.

12 Although guides such as guides 330 provide a convenient structural element for
13 appropriately orienting and approaching the compression plates of this invention relative
14 to each other, the appropriate orientation and relative displacement of the compression
15 plates can be achieved in other ways that accomplish the same effects as discussed for
16 example in reference to compression plate apparatus 300'. These different ways of
17 providing the appropriate relative orientation of the compression plates and the relative
18 displacement are within the scope of this invention. For example, a device used to hold
19 the compression plates as shown in FIG. 6D-6E, FIG. 12C-12G, and FIG. 16C can
20 provide the appropriate support for orienting and displacing the compression plates
21 relative to each other. Similarly, the cutting device may be configured to provide the
22 appropriate orientation.

23 FIGS 12A-12B provide a perspective view of snap-fit compression plate
24 anastomosis apparatus 300'. Like guided compression plate apparatus 300, snap-fit
25 compression plate apparatus 300' has two opposing compression plates including a first
26 compression plate 310a' and a second compression plate 310b'.

1 First compression plate 310a' has a ring 312a' with an inner periphery 311' and
2 an outer periphery ~~313~~ 311a'. A plurality of holding tabs 314a' extend from ring 312a'.
3 Like holding tabs 314a, each holding tab 314a' has a base 316a' and terminate at a distal
4 rounded tip 315a'. The base of each tab is preferably integral, as shown, with ring 312a'.
5 Each holding tab 314a' extends at its base from ring 312. More particularly, each
6 holding tab 314a' extends from inner periphery ~~311~~ 313a' from exterior side 324a'
7 toward anastomosis side 322a' (~~not shown~~).

8 Holding tabs 314a' extend either perpendicularly from ring 312a' of first
9 compression plate 310a' or curve inward from exterior side 324a' of ring 312a' of first
10 compression plate 310a' such that distal rounded tips ~~316~~ 315a' of holding tabs 314a' are
11 perpendicularly oriented relative to exterior side ~~32~~ 324a' of ring 312a' of first
12 compression plate 310a'. Like holding tabs 314a, holding tabs 314a' may have varying
13 configurations and various numbers of holding tabs may be utilized.

14 First compression plate 310a also has a plurality of locking arms 350 extending
15 from outer periphery 311a'. Locking arms 350 are adapted to lock with a locking
16 extension 360 projecting from second compression plate 310b'. Engagement of these
17 locking components enables compression plates 310a'-310b' to lock together such that
18 the portion 26 defining the first vessel opening 24 and the portion 56 defining the second
19 vessel opening 54 are joined without being penetrated as the first vessel and the second
20 vessel are anastomosed together.

21 Locking arms 350 have a length that enables them to lock around locking
22 extension 360 in a manner such that the portion defining the first vessel opening and the
23 portion defining the second vessel opening are held together without being damaged in a
24 manner that causes the anastomosis to fail. Each locking arm 350 has a pivot portion 352
25 that terminates at a grasping portion 354. Grasping portion 354 is preferably a curved
26 portion of locking arm 350 directed annularly inward.

1 Second compression plate 310b' has a second compression plate opening 320b',
2 or more precisely, an anastomosis side opening 320b', defined by a holding surface 364.
3 Second compression plate opening 320b' may also be described as being defined by rim
4 368 which is the point at which holding surface joins tubular portion 370. Holding
5 surface 364 extends radially downward at an angle from anastomosis side opening 320b'
6 and terminates at locking extension 360 such that second compression plate 310b' flares
7 in diameter from second compression plate opening 320b' down to locking extension
8 360. Locking extension 360 has two surfaces, a flaring surface 362 that is continuous
9 with holding surface 364 and a locking surface 366 shown in FIG. 12C-12G. While
10 locking extension is shown having a flaring surface 362 that is a continuous extension of
11 holding surface 364, these surfaces may also be distinct.

12 Holding surface 364 has a configuration that permits the portion of the second
13 vessel 50' defining the second vessel opening 54' to be everted onto holding surface 364
14 as shown in FIG. 12B. The vessel shown in FIG. 12B everted on holding surface 364 is
15 an autologous or heterologous blood vessel 50'. Of course, a graft vessel like vessel 50
16 can also be used, however, vessel 50' is identified as being autologous or heterologous in
17 order to depict the use of vessels that are not artificial. Everted portion 56' of vessel 50'
18 is preferably adhered onto holding surface 364 through the use of an appropriate adhesive
19 such as those described above in the Background section or attached through the use of
20 stay sutures or other means for holding vessel in an everted position. While holding
21 surface is shown extending radially downward at an angle from the second compression
22 plate opening, it may have any surface that is suitable for everting the portion of vessel
23 50' that defines opening 54' and for holding the everted portion 56'.

24 As shown in FIG. 12B, tubular portion 370 is adapted to receive vessel 50'
25 through exterior side opening 372 such that graft vessel can pass through anastomosis side
26 opening 320b' and be everted onto holding surface 364. As shown in FIG. 12G, exterior

1 side opening 372 is defined by tubular portion 370 and locking surface 366. The farther
2 that locking surface 366 extends from exterior side opening 372 the greater the distance
3 between vessel 50' and grasping portion 354 once the anastomosis is complete. Tubular
4 portion 370 may have an extension to provide further protection for vessel 50' against
5 contact with grasping portion 354. Tubular portion 370 may have a slanted orientation
6 corresponding to the angled orientation of holding surface 364. However, tubular portion
7 is preferably configured such that it has parallel sides as such a configuration enables the
8 barrier between grasping portion 354 of locking arms 350 and vessel 50' to be
9 maximized.

10 Holding tabs 314a' are additional examples of holding means for holding a
11 portion of a first vessel that defines a vessel opening in manner such that the portion
12 defining the vessel opening is at least partially everted and is preferably not penetrated.
13 Holding surface 364 is a also an example of holding means for holding a portion of a first
14 vessel that defines a vessel opening preferably in manner such that the portion defining
15 the vessel opening is at least partially everted and is preferably not penetrated.

16 FIGS. 12C-12G provide a sequential presentation of the steps involved in
17 utilizing
18 snap fit compression plate apparatus 300' as an anastomosis fenestra is formed in first
19 vessel 20 and as the compression plates are brought together to approximate vessel 20
20 and vessel 50. The sequential steps depicted in FIGS. 12C-12G are similar to steps
21 depicted in FIGS. 4A-4D for the use of guided compression plate apparatus 300.
22 However, FIGS. 12C-12G also show the use of attachment actuation device 600' having
23 a first plate engager 600a' and a second plate engager 600b'. Attachment actuation
24 device 600' is slightly different from attachment actuation device 600, which is described
25 in reference to FIGS. 6A-6E in detail in the section entitled External Anastomosis
26 Operator, in that it is not necessary to utilize the optional adapters 610a-b since first and

1 second compression plates 310a'-310b' are directly engaged. Each plate engager 600a'-
2 600b' has a component or a portion that directly contacts the plate in a configuration such
3 that the plate is held in a locked manner or such that the plate can be moved. A plurality
4 of screws 615a' lock first compression plate 310a' in place while extension 615b' of
5 second plate engager 600b' pushes second compression plate 310b'. First compression
6 plate 310a' may have recesses for receiving screws 615a'.

7 FIG. 12C depicts anvil 210 extending through first compression opening 320a
8 with its landing 214 abutting first holding tabs 314a while cutter 400 and second
9 compression plate are opposite spherical engaging end 212 with anvil pull 230 extending
10 through cutter 400. FIG. 12D depicts cutting edge 414 pressing against spherical
11 engaging end 212 above the portion where spherical engaging end terminates at landing
12 214.

13 FIG. 12E depicts compression plate apparatus 300' as it is being compressed and
14 as portion 26 defining vessel opening 24 is being everted. More particularly,
15 compression plate 310b' has been moved toward compression plate 310a' as second
16 plate engager 600b' is pushed toward first plate engager 600a'. Note that the everted
17 portion 56' of graft vessel 50', more particularly the portion 57' opposite from the rim
18 368, is urged against portion 26 that defines first blood vessel opening 24 in a manner
19 such that portion 26 is being everted. This eversion process is augmented by landing 214 of
20 anvil 210 which allows portion 26 to rest on landing 214 and be plowed upward by
21 everted portion 56'. The length of portion 26 is sufficient for this eversion process since
22 vessel 20 was distended and pulled into the snap-fit compression plate apparatus by the
23 action of anvil 210. FIG. 12E also depicts grasping portion 354 sliding on flaring surface
24 362 as pivot portion 352 extends radially outward.

25 FIG. 12F depicts portion 26 fully everted on holding tab 314a' such that portion
26 27 opposite from rounded tip 316 315a' is held in contact with the portion 57' of vessel

1 50 opposite from rim 368. After compression plate apparatus 300' has been compressed
2 to join portion 26 of blood vessel 20 that defines first vessel opening 24 to portion 56' of
3 second vessel 50' that defines graft vessel opening 54' then first vessel 20 and second
4 vessel 50 are anastomosed together and are in fluid communication. Anvil apparatus 200
5 and cutter 400 have been removed upon the completion of the procedure through lumen
6 58 of graft vessel 50. More particularly, once the anastomosis is completed then anvil
7 pull 230 is pulled so that it draws anvil 210 through openings 320a, 320b' and 372 of
8 compression plate apparatus 300' such that anvil apparatus 200 is removed along with
9 cutter 400 through lumen 58'. FIG. 12G depicts vessel 20 anastomosed to vessel 50'
10 after attachment actuation device 600' has been removed.

11 The mated locking components of first compression plate 300a' and second
12 compression plate 300b', namely locking arms 350 and locking extension 366, are
13 adapted to lock the compression plates together such that portion 26 defining first vessel
14 opening 24 and portion 56' defining the second vessel opening 54' are joined without
15 being penetrated. Such locking components are an additional example of means for
16 locking the compression plates together. Note these locking means are integral parts of
17 each compression plate so it is not necessary to separately attached the locking means to
18 the compression plate apparatus after it has been used to anastomose the vessels.

19 FIG. 13 depicts another embodiment of a guided compression plate apparatus
20 300'' which has components that are almost all identical with those of compression plate
21 apparatus 300 except that the components of compression plate apparatus 300'' are
22 oriented for use with a non-perpendicular anastomosis. Note that the end of vessel 50 has
23 been cut at an angle so that it can be attached to a vessel as shown in FIG. 14C at an
24 angle. Cutter 400' is also angled so that it can make a cut in a vessel that is elliptical in
25 configuration. Openings 320a''-320b'' are also elliptical so that the aligned openings of
26 compression plate apparatus 300', the first vessel opening and the second vessel opening

1 are all elliptical. Guides 330'' do not extend perpendicularly from ring 312a'' like guides
2 330. Guides 330'' are all parallel to each other and extend nonperpendicularly from ring
3 312a'' so that guide compression plate apparatus 300'' is shaped like a parallelogram.
4 Guide apertures 334'' are also formed with the same angled configuration of guides
5 330''. This configuration enables compression plates 310a''-310b'' to be brought
6 together in a manner such that second compression plate 310b'' is moved in a fixed
7 parallel orientation relative to first compression plate 310a''.

8 Holding tabs 314a-b'' may also be configured differently than holding tabs
9 314a-b in order to hold angled noncircular vessel openings. Note that guides 330''
10 extend integrally from ring 312'' and are not attached. Another difference is the use of
11 guide barbs 336 to provide for irreversible advancement of second compression plate
12 310b'' towards first compression plate 310a'' as discussed above with regard to frictional
13 engagements to prevent movement of the plates relative to each other after anastomosis.
14 Note that while snap-fit compression plate apparatus 300' is shown being used for joining
15 vessels with openings that are generally circular, the same principles shown with regard
16 to apparatus 300'' can also be used to modify apparatus 300' for use with noncircular
17 openings.

18 Compression plate apparatus 300, 300' and 300'' are all examples of means for
19 joining a portion of the first vessel that defines the first vessel opening to a portion of a
20 second vessel that defines a second vessel opening. More specifically, they are examples
21 of means for mechanically joining the portion of the first vessel that defines the first
22 vessel opening to the portion of the second vessel that defines the second vessel opening.
23 Other examples of means for mechanically joining the vessels include suture thread,
24 staples, clips, and combinations thereof. An example of the use of staples or clips is
25 shown in FIG. 14C.
26

1 The joining means also includes means for chemically joining the vessels.
2 Examples of means for chemically joining the vessels include biocompatible adhesives or
3 glue; solder; biological procoagulant solution; a combination of a chromophore and
4 solder, and combinations thereof. These materials are discussed in detail in the
5 Background section. Figure 14D depicts such materials being delivered in accordance
6 with one embodiment.

7 The joining means also includes radiation-based means for joining the vessels.
8 Examples of radiation-based means for joining the vessels include tissue welding
9 radiation; the combination of substances and radiation for laser sealing, and combinations
10 thereof. The use of radiation for joining vessels is discussed in detail in the Background
11 section. Figure 14D also depicts radiation being delivered to join vessels.
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Cutting Devices

1 The term “cutter” is used to refer to a tubular knife such as cutter 400. Cutter
2 400 is an example of a “cutting device” which is a term used to refer to cutters and any
3 other instrument used to form an anastomosis fenestra or opening that does not rely on
4 the application of mechanical pressure, such as cutting device 400”. While cutters that
5 use a radiation source, such as a surgical laser, that emit radiation of the appropriate
6 characteristics to open the anastomosis fenestra in the receiving blood vessel wall are
7 useful, cutting devices such as cutter 400 are generally less expensive. Cutter 400 is
8 preferably formed from stainless steel such that it is sufficiently inexpensive to be a
9 disposable, single use item. These cutting devices disclosed herein are all examples of
10 cutting means for forming an opening in the wall of the first vessel at the anastomosis site
11 through engagement with the anvil of an anvil apparatus as an engaging means holds the
12 anvil pull of the anvil apparatus after receiving the anvil pull through the cutting means.
13 The cutting devices engage an anvil to form the vessel opening in any suitable manner.
14 For example, the cutting device may be pushed against the anvil, the anvil may be pulled
15 against the ~~cutter~~ cutting device or both may simultaneously occur such that the anvil is
16 pulled as the ~~cutter~~ cutting device pushes against the anvil.

17 Cutter 400 is shown in numerous drawings, however, FIGS. 6C-6E, show its full
18 length and its use in combination with external anastomosis operator 700. FIG. 6E
19 provides the best view of cutter 400. Cutter 400 is shown in FIG. 6B-E as including a tip
20 portion 401 and an extension portion 402, however, cutter 400 is shown elsewhere as
21 being integral.

22 Anvil pull 230 is shown in FIG. 6C extending through cutter 400. Cutter 400 is
23 hollow so it has a chamber 420 between the sidewalls of cutting tube 410. Cutter 400
24 may also have an optional centering core 422 that extends at least part way though
25 chamber 420. Centering core 422 has a centering conduit 424 that assists in centering
26

1 anvil pull 230 in cutter 400 such that anvil pull 230 is essentially parallel with the
2 sidewalls of cutting tube. Centering core 422 preferably has a tapered access to guide
3 anvil pull 230 into centering conduit 424. Another example of a centering conduit is
4 provided by a centering conduit 424' of cutting device 400' shown in FIG. 14D, as
5 discussed below in greater detail.

6 It is not always necessary for cutter 400 to have a centering core or for other
7 cutting devices to have a centering core or a centering conduit. When the engaging end
8 of the anvil is spherical and the cutter is spherical and is configured such that it permits
9 part of the spherical engaging end of the anvil to be positioned in cutter chamber 420 then
10 the cutter self centers on the spherical engaging end. The entire cutting device need not
11 be hollow. For example, cutting device 400'' has a recess 428 at its cutting end that is
12 deep enough to permit the engaging end of anvil 200d' to extend into recess 428 so that
13 anvil 200d' may be centered and seated. Accordingly, the cutting end is preferably
14 adapted to receive a portion of the engaging end into the cutter to enable the engaging
15 end to self center and be seated. Also, the engaging end is preferably convex and more
16 preferably spherical.

17 As shown in FIG. 6C, cutter 400 is spring biased by a spring biasing device 450
18 that is described in detail below in the External Anastomosis Operator section. However,
19 to appreciate the benefits of spring biased cutting it should be understood that distal end
20 418 of cutter 400 is received into a moveable cutter cup 458 which can push against
21 spring 460. The pressure of spring 460 against cutter cup 458 enables cutter 400 to apply
22 pressure against anvil 210 as anvil 210 is pulled against cutter 400. This makes it easier
23 to cut the vessels as force is being applied in both directions. More particularly, it
24 reduces the amount of force that would otherwise be required if the only force being
25 applied was through the advancement of anvil 210 by pulling anvil pull.
26

1 A spring _biased cutter also enables the cutter to be pushed back by anvil 210 to
2 allow anvil 210 to further distend the wall of vessel 20 as shown in FIGS. 4A-4B, FIGS.
3 6D-6E, FIGS. 12C-12E, FIGS 15B-15C and FIGS. 16D-16E. As anvil 210 pushes
4 cutter 400 through vessel 20, anvil 210 causes cutter 400 to retract, however, increasing
5 resistance is encountered as spring 460 becomes further compressed. So cutter 400
6 applies increasing amounts of pressure to vessel 20 as anvil 210 continues to stretch the
7 wall of vessel 20 into compression plate apparatus 300. By optimizing features such as
8 the tension of the spring and the length of the cutter, vessel 20 is distended far enough
9 into compression plate apparatus 300 to leave sufficient lengths of the vessel in the
10 compression plate apparatus for capturing in the subsequent eversion process onto
11 holding tabs 314a. It has been found that about 17 -18lbs or about 20 lbs is generally
12 required to form the anastomosis fenestra.

13 The gradual increase in pressure also serves to assist a spherical engaging end
14 212 of anvil 210 to self center on cutter 400. ~~Since the pressure increases gradually, if~~ If
15 anvil 210 is initially misaligned on cutter 400 then the gradual increase in pressure causes
16 the anvil to be gradually drawn to center as the spherical engaging end 212 is pulled into
17 chamber 420 or recess 428 of the cutting device. If pressure is applied too rapidly, the
18 sharp cutting edge 414 of a cutter such as cutter 400 may dig into anvil 210 before anvil
19 210 can slide into a centered orientation. Accordingly, the use of a cutter with at least a
20 recess at its cutting end and a spherical engaging end accommodates imperfections in the
21 alignment of the cutter and the anvil.

22 FIGS. 14A-14B depict a simple combination of a cutter engaging an anvil as the
23 anvil pull 230''' is advanced by an anvil pull engager 500' which holds and advances
24 anvil pull 230'''. Note that distal end 232 of anvil pull 230 is threaded and anvil pull
25 engager is essentially a wingnut that is correspondingly threaded. As anvil pull engager
26 500' tightens against the distal end 418 of cutter 400 then anvil pull 230 pulls anvil 200

1 until cutter 400 is engaged. Of course, an even simpler design is the manual application
2 of pressure by pulling on anvil pull while pushing on cutter without an anvil pull engager.

3 FIG. 14C depicts an anastomosis fenestra formed through the use of a cutter such
4 as cutter 400'. Cutter 400' works in the same way as cutter 400 except that anvil 200b'
5 has an elliptically shaped engaging end and cutter 400 has an elliptically shaped and
6 angled cutting knife 412' and cutting edge 414'. Such a combination of an anvil with an
7 elliptically shaped engaging end and a mated cutter with an elliptically shaped and angled
8 cutting knife and cutting edge enable anastomosis to be formed as shown in FIG. 14C
9 that involves the nonperpendicular attachment of a vessel to a side of another vessel.
10 The configuration of the opening and the diameter of the opening to be formed depends
11 on factors such as whether the opening is for a venotomy or an arteriotomy.

12 After the opening is formed by cutter 400' then the vessels may be joined in the
13 same way that a vessel is joined perpendicularly to a side of another vessel. For example,
14 the portions defining the openings may be clipped or ~~staples~~ stapled together through the
15 use of a clipping or stapling device 800 that delivers clips ~~800~~ 810 or staples. If the
16 vessels are mechanically joined through the use of sutures, staples or clips then it may be
17 desirable to enhance the leak proof character of the anastomosis through the use of laser
18 welding with a conventional laser welding device, such as an endoscopic laser welding
19 devices. Similarly, the seal may be augmented through the appropriate use of
20 biocompatible adhesives administered by conventional delivery devices, including
21 endoscopic glue delivery devices. Additionally, a seal may be formed or strengthened by
22 techniques such as laser soldering, including chromophore-enhanced laser soldering, and
23 laser sealing.

24 FIG. 14D depicts a device identified as cutter 400'' which may be used to form
25 the anastomosis fenestra to permit the angled attachment shown in FIG. 14C. Cutter
26 400'' has an element 430 that may be embodied by a surgical laser such as a cluster of

1 optical fibers 432 that delivers appropriate radiation. Cutter 400'' also has an applicator
2 440 for delivering a fluid 442 such as biocompatible adhesives or glue; solder; biological
3 procoagulant solution; a combination of a chromophore and solder, and combinations
4 thereof. These materials may be delivered after the element 430 has been used or
5 simultaneously depending on the objective. For example, if fluid 442 is an adhesive then
6 applicator 440 can deliver the adhesive in a controlled manner after the radiation has been
7 delivered to ablate the vessel wall to open the anastomosis fenestra. However, when
8 utilizing element 430 for welding radiation or laser sealing then fluid 442 is preferably
9 delivered before or is simultaneously delivered. Also, cutter 400'' may be used only to
10 deliver glue after a mechanical cutter such as cutter 400' has been used. Adhesives and
11 solder may be used alone, or as discussed above, adhesives and solder may be utilized to
12 further seal an anastomosis that utilizes a mechanical devices such as clips as shown in
13 FIG. 14C.

14 **External Anastomosis Operators**

15 The positioning of the compression plate apparatus and the operations of pulling
16 or holding anvil pull 230, making an opening, and compressing the compression plates
17 together as described in the foregoing sections can be accomplished by manually
18 actuating these elements or with the aid of devices such as external anastomosis operator
19 700. One advantage derived form the use of a device such as external anastomosis
20 operator 700 is that such devices have a series of actuators, and by manipulating these
21 actuators the operator can effectuate the different operations at the anastomosis site
22 without actually having to manually and directly operate each element itself.

23 As shown in FIG. 6A, external anastomosis operator 700 has a body 710 with an
24 optional handle 720. Attached to body 710, are the main components of operator 700, as
25 identified in FIG. 6A. These main components are cutter 400, spring biasing device 450,
26

1 an anvil pull engager 500 which includes an anvil pull holder 530 and an anvil pull
2 advancer 560, and an attachment actuation device 600.

3 FIG. 6B provides an exploded perspective view of all of the components of
4 external anastomosis operator 700 so it is with reference primarily to this view that the
5 details of operator 700 are understood. FIGS. 6C-6E provide cross-sectional views of
6 operator 700 depicting the steps for using operator 700.

7 Cutter 400 is shown in FIG. 6B-E as including a tip portion 401 and an extension
8 portion 402. Note that cutter 400 is shown elsewhere as being integral. The advantages
9 of using a spring biasing device 450 to apply pressure against the distal end 418 of cutter
10 400 are explained above in the Cutting Devices section. However, the components of
11 spring biasing device 450 are described in this section.

12 Spring biasing device 450 has a spring mount 452 that is mounted to body 710
13 via spring mount pins 454. A rotatable spring housing 456 is threadably engaged by
14 spring mount 452. Loaded into rotatable spring housing 456 is a cutter cup 458 that is
15 configured to hold distal end 418 of cutter. Cutter cup 458 has a flange that is pushed
16 against a flange at the proximal end of rotatable spring housing 456 such that cutter cup
17 458 is held in the proximal end of spring housing 456. A spring 460 is positioned within
18 a spring sleeve 462. Spring 460 and spring sleeve 462 have ends that abut cutter cup 458
19 and opposite ends that abut threaded jam screw 464. Threaded jam screw 464 is
20 accessible via the distal end of spring mount 452 so that it may be rotated to increase or
21 decrease the tension of spring 460 against cutter cup 458.

22 Cutter cup 458 moves within rotatable spring housing 456 against spring 460.
23 As discussed generally above in the Cutting Devices section, the pressure of spring 460
24 against cutter cup 458 enables cutter 400 to apply pressure against anvil 210 as anvil 210
25 is pulled against cutter 400. This makes it easier to cut the vessels as force is being
26 applied in both directions. It also enables cutter 400 to be pushed back by anvil 210 to

1 allow anvil 210 to further distend the wall of vessel 20 as shown in FIGS. 4A-4B until
2 sufficient pressure is applied by spring 460 to bias cutter 400 forward and by the
3 advancement of anvil 210 by anvil pull 230 to cut the vessel. The gradual increase in
4 pressure also serves to assist a spherical engaging end 212 of anvil 210 to self center on
5 cutter 400. More particularly, anvil 210 may be initially misaligned such that the center
6 of engaging end from which anvil pull extends is positioned on cutting edge 414. A rapid
7 application of pressure would lock such a misalignment while a gradual increase enables
8 the curvature of spherical engaging end to guide the anvil into a centered orientation.

9 Another function of spring biasing device is to set the position of cutter 400.
10 Rotatable spring housing 456 has a notch 457 at its distal end that enables a screw driver
11 to rotate rotatable spring housing 456 within spring mount 452 to advance or retract
12 rotatable spring housing 456 within spring mount 452. Movement of rotatable spring
13 housing 456 also moves cutter cup 458, thereby determining the location of distal end
14 418 of cutter 400 within operator 700. Of course advancement of cutter cup 458 towards
15 the proximal end of operator 700 causes cutting knife 400 to be engage anvil 210 closer
16 to first compression plate 310a while retraction of cutter cup 458 towards the distal end
17 of operator 700 causes cutting knife and anvil to engage each other closer to second
18 compression plate 310b. The position of cutter 400 is preferably set to enable vessel 20
19 to be distended in a manner that is optimal for then subsequently everting the portion
20 defining the newly formed opening onto holding tabs 314a. To carefully identify the
21 length that rotatable spring housing 456 is advanced or retracted, a detent 470 is threaded
22 into spring mount such that it can contact rotatable spring housing and engage the
23 grooves 471 of rotatable spring housing in a manner that enables detent 470 to click as
24 each groove is rotated past detent 470.

25 Obviously spring biasing device 450 has many variables that impact the manner
26 in which cutter 400 is used in combination with external anastomosis operator 700.

1 Some of these variables include the inherent tension of spring 460, the tension of spring
2 460 as caused by the position of threaded jam screw 464 in spring mount 452 against
3 spring 460, and the position of the surface which distal end 418 of cutter 400 abuts,
4 namely cutter cup 660 as determined by the position of rotatable spring housing 456
5 within spring mount 452.

6 Spring biasing device 450 is an example of spring biasing means for providing
7 tension against the cutting means as the cutting means engages the anvil means of the
8 intraluminally directed anvil apparatus. The spring biasing means provides an amount of
9 tension that enables the cutting means to form the first vessel opening after the wall of the
10 first vessel has been distended by the action of the anvil means being pulled into the
11 openings of the compression plate assembly such that forming the first vessel opening
12 results in at least partial eversion of the portion of the first vessel defining the first vessel
13 opening.

14 As indicated above, anvil pull engager 500 has two primary components
15 including an anvil pull holder 530 and anvil pull advancer 560. Anvil pull holder 530
16 receives anvil pull 230 via spring biasing device 450. More particularly, anvil pull 230
17 extends through cutter cup 458, rotatable spring housing 456, spring 460 and sleeve 462
18 around spring 460, and out of threaded jam screw 464.

19 Anvil pull holder 530 includes a holder mount 532 positioned in track 730 of
20 body 710. In this embodiment, holder mount 532 is moveable so that the anvil pull can
21 be advanced after it is held. However, in other embodiments, the anvil pull holder may
22 just lock the anvil pull into position such that the cutter is moved against a stationary
23 anvil. Similarly, the spring biasing device 450 may be eliminated so that the vessel is cut
24 only by pressure exerted by the anvil pull against the cutter. As discussed above, while
25 the cutter and the anvil may engage each other in these arrangements, it is preferable for
26 the cutter to apply some pressure as the anvil pull is advanced against the cutter.

Holder mount 532 may be utilized in different ways to hold anvil pull 230. Holder 530 has a split cone 534 inserted into a tapered chamber 536 against a spring 538. Anvil pull 230 extends through apertures in holder mount 532, spring 538, split cone 534 and out of an aperture centered in holder knob 540. Holder knob 540 is threadably engaged by holder mount 532 such that rotation of holder knob 540 advances split cone 534 in tapered chamber 536 causing split cone to lock onto anvil pull 230. ~~As shown in FIG. 6B, holder~~ Holder mount is 532 may be slotted at its distal end, as is may holder knob, 540. By aligning the slot 542 (not shown) of holder knob 540 with the insert slot 544 (not shown) of holder mount, 532, anvil pull 230 can be bent so that it extends through both the holder knob slot 542 and the insert slot 544. ~~Then holder~~ Holder knob 540 can then be rotated so that the bent portion of anvil pull 230 is rotated into one of the locking slots 546a-b (not shown) that extend perpendicularly from the insert slot 544. This securely locks anvil pull 230 into position. Anvil pull 230 can be locked through the use of slots instead of or in addition to the use of split cone 534 in tapered chamber 536.

The anvil pull holders described herein are examples of holding means for holding the anvil pull extending from an anvil. The anvil pull advancers described herein are examples of advancement means for pulling the anvil pull once the anvil pull is held by the holding means. As indicated above, the anvil pull holder may have a fixed position such that it is not moveable. As also indicated above, however, the anvil pull holder is preferably moved via an anvil pull advancer. A fixed anvil pull holder and an anvil pull holder that is moveable via an anvil pull advancer are both examples of an anvil pull engagers. The anvil pull holder and the anvil pull advancer may be separate components such as anvil pull holder 530 and anvil pull advancer 560 or be embodied by a component capable of both holding and advancing the anvil pull such as anvil pull engager 500' shown in FIGS. 14A-14B. These anvil pull engagers are all examples of engaging means for holding an anvil pull extending from an anvil. Once such engaging

1 means holds the anvil pull then the engaging means can control the position of the anvil
2 at the anastomosis site via the anvil pull.

3 Since anvil pull holder 530 is moveable, it threadably engages rotatable lead
4 screw 562 of anvil pull advancer. More particularly, lead screw 562 is threadably
5 engaged by anti-backlash nut 550 which is fixedly attached to holder mount 532. Anti-
6 backlash nut 550 has an attachment face 552 through which a plurality of attachment face
7 screws 554 extend to hold holder mount 532 and anti-backlash nut 550 together.

8 Lead screw 562 has a proximal pivot end 564 that rotates within a bushing 566
9 positioned within a recess in spring mount 452. Lead screw also has a distal pivot end
10 568 that is attached to advancer knob 570 to rotate lead screw 562. Advancer knob 570
11 rotates within an advancer knob mount 572 which is attached to body 710 in groove 730
12 via advancer knob mount bolts 574. As shown in FIG. 6C, distal pivot end 568 rotates in
13 a bushing 576 positioned within an aperture of advancer knob mount 572.

14 Advancer knob 570 has a stem with a plurality of grooves 578 that engage a
15 detent 580 to click so that the incremental rotation of advancer knob 570 can be carefully
16 counted to determine the length that the anvil is moved in the compression plate
17 apparatus as the anvil pull is advanced. As shown in FIG. 6C, detent 580 is threaded into
18 advancer knob mount 572 such that it can contact grooves 578 in the stem of advancer
19 knob 570 to click as each groove is rotated past detent 580.

20 FIG. 6D depicts advancer knob 570 being rotated to move anvil pull advancer
21 560 so that it can urge anvil pull 230 in a manner such that anvil 210 is advanced within
22 compression plate apparatus 300. As advancer knob 570 is rotated, lead screw 562 is
23 thereby rotated. Since anvil pull holder 530 is threadably engaged on rotatable lead
24 screw 562 and is locked in track 730, anvil pull holder 530 can only move forward and
25 backward as lead screw 562 is rotated.
26

1 FIG. 6E depicts attachment actuation device 600 being engaged. Attachment
2 actuation device 600 has a first plate engager 600a and a second plate engager 600b.
3 First plate engager 600a and a second plate engager 600b each respectively utilize an
4 optional adaptor 610a-b to engage first and second compression plates 310a-b. Note that
5 attachment actuation device 600' described in reference to FIGS. 12CA-12G does not
6 utilize these optional adapters since its first and second plate engagers 600a'-600b' are
7 adapted to directly engage first and second compression plates 310a'-310b'.

8 First plate engager 600a and second plate engager 600b each have a cutter
9 aperture 620a and 620b, as shown in FIG. 6B. Cutter 400 extends through these aligned
10 apertures 620a-b. First plate engager 600a is positioned on rail 640 such that it extends
11 slightly beyond cutting edge 414 of cutter 400. This difference in length enables first
12 compression plate 300a to be held slightly beyond cutter 400 in a manner that permits the
13 wall of vessel 20 to be pulled into compression plate apparatus 300 as shown in FIG. 6D-
14 6E and distended as needed.

15 Rail 640 is attached to body 710 via rail pin 642. A groove pin 644 extends
16 through rail 640 as described in greater detail below. A first plate engager pin 646 holds
17 first plate holder 600a on the proximal end of rail 640.

18 First plate engager 600a is fixedly mounted on rail 640 via pin 646 while second
19 plate engager 600b is movably mounted on rail 640. Second plate engager 600b has a
20 groove 634 through which groove pin 644 extends. The configuration of groove pin 644
21 in groove 634 enables second plate engager 600b to be held in a fixed orientation such
22 that it can be moved back and forth as needed with respect to first plate engager 600a.

23 Second plate engager is moved on rail 640 by rotating threaded compressor
24 sleeve 650 which engages a threaded rail sleeve 648. Threaded rail sleeve 648 may be
25 adhered onto rail 640 or be an integral component. Rail 640 and its threaded rail sleeve
26

648 or threaded rail portion combined with compressor sleeve 650 are means for advancing one plate engager towards the other plate engager.

First plate engager 600a has an adaptor 610a that preferably has two halves 612a and 614a. As best seen in FIGS. 6C, when these halves are joined together, adaptor 610a has a proximal side configured such that there is a curvature from the perimeter inward to direct the engaging end 212 of anvil 210 into the aperture defined by the inner perimeter of adaptor 610a. The distal side of adaptor 610a has a recess 616 adapted to the size of outer periphery 311a of first compression plate 310a. Sets screws 615 lock first compression plate 310a in place by pushing against adaptor 610a. Note that there are many other ways for locking first compression plate with first plate engager 600a such as the use of conventional quick release configurations.

Second plate engager 600b has an adaptor 610b or 610b' as respectively shown in FIGS. 5A-5B. Adapter 610b is integral while adapter 610b' has halves 612b and 614b. Either may be utilized, but when positioned on a graft vessel as shown in FIG. 5B that has reinforcements 57, which may be any conventional reinforcements such as fluorinated ethylene-propylene (FEP) strands bonded onto a PTFE graft vessel, the reinforcements make it difficult to remove the adapter that it integral like adaptor 610b. As best seen in FIG. 5A, adaptor 610b is tubular to receive the vessel and has a flange 616b that extends around the tube and is sized to push against exterior side 324b of second compression plate 310b. Apertures 618b are located in flange 616b that are oriented and sized to slidably receive guides 330 of compression plate apparatus 300. Adapter 610b also has a flange with apertures so that it can fit over second compression plate 310b as shown in FIG. 5B. These features are more clearly shown in FIG. 6C which provides a cross-sectional view of assembly 390 shown in FIG. in FIG. 5B. Note that adaptor 610b is also shown in FIG. 16C, which is a close-up view of the proximal portion of applicator 700, however, adaptor 610b is pushed back from its position of

1 engagement with second compression plate 310b in order to more clearly see other
2 features of operator 700.

3 As discussed below in the Side-to-Side Anastomosis section in reference to FIG.
4 15A-15C, the attachment actuation device need not be part of the same apparatus with the
5 anvil pull engager and the cutter. FIGS. 15A-15C show a device at 600a'' that is adapted
6 to hold the first compression plate stationary as the anvil and the cutter are engaged.
7 Device 600''' is also discussed below in reference to FIG.15A-15C which is used to
8 approximate compression plates 310a-b by pushing second compression plate 310b on
9 guides 330. Attachment actuation device 600, 600' and 600''' are examples of
10 attachment actuation means for actuating a compression plate assembly. In addition to
11 device 600, 600', and 600''', device 600a'' is also an example of an attachment
12 actuation device adapted to hold the first compression plate stationary as the anvil and
13 cutting device are engaged to form an opening. As noted above, compression plate
14 apparatus 300, 300', 300'' are examples of means for joining a portion of the first vessel
15 that defines the first vessel opening to a portion of a second vessel that defines a second
16 vessel opening. Accordingly, attachment actuation device 600 is more broadly an
17 example of attachment actuation means for actuating means for joining a portion of the
18 first vessel that defines the first vessel opening to a portion of a second vessel that defines
19 a second vessel opening.

20 Other examples of attachment actuation means include mechanical, chemical or
21 radiation-based attachment actuation means for actuating the anastomosis of the portion
22 of the first vessel that defines the first vessel opening to the portion of the second vessel
23 that defines the second vessel opening. Examples of mechanical attachment actuation
24 means

25 include a suturing device such as a needle and thread; and a stapling or clipping device
26 such as device 800. Examples of chemical attachment actuation means include a device

1 such as device 400'' for delivering biocompatible adhesives or glue; solder; biological
2 procoagulant solution; a combination of a chromophore and solder, and combinations
3 thereof. Examples of radiation-based attachment actuation means include a device such
4 as device 400'' for radiation welding, a device for laser sealing, and combinations
5 thereof. As shown by device 400 and 800, combinations of these attachment actuation
6 means are also possible.

7 As mentioned, the attachment actuation device need not be part of the same
8 apparatus with the anvil pull engager and the cutter. This reduces the size of the
9 instruments utilized. The size of the instruments utilized may also be decreased through
10 the elimination of some of the features of operator 700. Operator 700 has the ability to
11 modify its configuration in ways that enable it to be highly fine tuned to the parameters of
12 a particular anastomosis procedure. Accordingly, it is highly useful in a research setting.
13 However, applicators utilized in a commercial setting may have more standardized
14 features that do not permit the same degree of modifications. For example, the spring
15 biasing device may be preset to a standard setting. Use of such standard settings may
16 assist in reducing the overall size of the operator. Note that the knobs and other features
17 of external anastomosis operator that provide adjustments may also be achieved through
18 other configurations that achieve these adjustments more rapidly. For example, instead
19 of rotating compressor sleeve 650, compression plate apparatus 300 may be compressed
20 through a configuration that is trigger activated.

21 As indicated above, anvil 210 may be positioned under direct image guidance
22 from a distant percutaneous puncture to the anastomosis site based upon a diagnostic
23 angiographic roadmap. A skin incision and limited vessel dissection is then performed at
24 the anastomosis site to expose the vessel wall. Alternatively, the anvil may be externally
25 positioned. In either event, once the anvil has been positioned such that it is against the
26 interior of the vessel wall and the anvil pull extends from the vessel, then the anvil pull

1 can be positioned in the operator 700 as shown in FIGS. 6C-6D for completion of the
2 anastomosis procedure.

3 **Side-to-Side Anastomosis**

4 FIGS. 15A-15C depict the primary steps involved in achieving a side-to-side
5 anastomosis. Cutter 400 is positioned in a vessel 50 by inserting the cutter into an end of
6 vessel 50 and then twisting cutter 400 in vessel 50 such that cutting knife 412 is oriented
7 towards the wall of vessel 50 as shown in FIG. 15A. Cutting knife 412 is prevented from
8 cutting through the wall of vessel 50 by a sheath 490. Sheath 490 is positioned relative to
9 cutter 400 such that the distal end 492 of sheath 490 extends beyond cutting edge 414.
10 This configuration prevent cutting edge 414 from contacting vessel 50 until sheath 490 is
11 pulled upward away from the anastomosis site.

12 Two separate instruments perform the task of attachment actuation device 600.
13 First plate engager 600a'' comprises tongs or pliers that have opposing grasping portion
14 602a'' that extend integrally from pivotally attached handle portions 604a''. Grasping
15 portions 602a'' are adapted to lock onto first compression plate 310a so that anvil 210
16 can be pulled through first compression plate opening 320a and distend the wall of vessel
17 20 into compression plate apparatus 300.

18 While first plate engager 600a'', holds first compression plate 310a cutter 400,
19 sheath 490 and vessel 50 are pushed through second compression plate opening 320b.
20 Note that anvil pull 230 extends through the wall of vessel 50 and through chamber 420
21 of cutter 400. As cutter 400 is pushed through compression plate apparatus 300 and
22 contacts anvil 230, sheath 490 is retracted.

23 FIG. 15B shows sheath 490 retracted so that cutter 400 and anvil 210 can engage
24 each other such that openings 24 and 54 are simultaneously made respectively in vessel
25 20 and in vessel 50. After opening 54 is made, the portion 56 defining second vessel
26

opening 54 rests on either sheath 490, cutting tube 410 or anvil 210. As the compression plates are brought together, portion 56 is advanced onto landing 214 against portion 26 of vessel 20 that defines first vessel opening 24.

FIG. 15B shows first and second compression plate apparatus being grasped by attachment actuation device 600". More particularly, attachment actuation device 600" has a first plate engager 600a" that engages first compression plate 310a and a second plate engager 600b" that engages first compression plate 310b such that the compression plates 310a-b can be approximated by pushing second compression plate 310b on guides 330.

FIG. 15C depicts attachment actuation device 600" after it has pushed second compression plate 310b to first compression plate 310a. As second compression plate 310b is pushed toward first compression plate 310a, portion 56 of vessel 50 pushes against portion 26 of vessel 20 as these portions rest on landing 214 which causes the portions to respectively curl onto holding tabs 314a-b. When the second compression plate 310b is fully pushed into position by attachment actuation device 600" then portions 26 and 56 are everted as shown on holding tabs 314a-b. Cut portions 25 and 55 remain on spherical engaging end 212 of anvil 210 and are removed with anvil apparatus 200, cutter 400 and sheath 490 through vessel 50.

It follows from the illustrations and the foregoing discussion that the compression plates of this invention can effectively be used for anastomoses at the end of tubular structures. This implementation of the teachings described above to end-to-end anastomosis simply requires ordinary skills in the art.

Externally Directed Anastomosis

Intraluminal access to the anastomosis site in the receiving blood vessel can be impeded by an occlusion or by blood vessel damage. In this case, a catheter cannot be

1 used to intraluminally access the anastomosis site. Instead, other embodiments of this
2 invention rely on the intraluminal access to the anastomosis site through a small incision,
3 such as an arteriotomy, made at the anastomosis site. The anvil apparatus is then inserted
4 through such incision and the abutting of the receiving blood vessel from its intraluminal
5 space is then performed in the same way as when the anvil and wire are inserted with the
6 aid of a catheter.

7 FIGS. 16A-16E depict the primary steps involved in creating an anastomosis
8 through the use of an externally positioned anvil apparatus in combination with an
9 external anastomosis operator. FIG. 16A depicts an insertion opening 16 that has been
10 made in vessel 20. Insertion opening 16 is preferably just large enough to permit an anvil
11 such as anvil 210c as shown in FIG. 7C or any of the other anvils disclosed herein to be
12 externally positioned into lumen 28. After anvil 210c has been inserted through a wall of
13 first vessel 20 at insertion opening 16 that has been selected as an anastomosis site such
14 that anvil pull 230 extends through insertion opening 16, then a stay suture 30 or several
15 stay sutures may alternatively be used to partially close insertion opening 16.

16 As discussed above, in relation to FIG. 7D, it may be easier to insert an anvil
17 extraluminally that has a tapered terminal end 218 such as terminal end 218c of anvil
18 210c or terminal end 219c of anvil 210d. Note that FIGS. 16C-16E, however, show an
19 anvil 210 that has been inserted from outside of vessel 20 that has a nontapered terminal
20 end 218.

21 As shown in FIG. 16C, anvil pull 230 can then be loaded into external
22 anastomosis operator 700 for the anastomosis procedure. Note that once anvil pull 230 is
23 loaded into external anastomosis operator 700 then the remainder of the procedure is the
24 same as the anastomosis procedure outlined above in reference to an intraluminally
25 positioned anvil apparatus.
26